IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR, ET AL	*	Civil Docket No.
	*	2:07-CV-139
VS.	*	Marshall, Texas
	*	
	*	June 23, 2009
ABBOTT LABORATORIES	*	1:15 P.M.

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE JUDGE T. JOHN WARD
UNITED STATES DISTRICT JUDGE
AND A JURY

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P R O C E E D I N G S

COURT SECURITY OFFICER: All rise.

(Jury in.)

THE COURT: Please be seated.

All right, Mr. Sayles. Let's continue.

MR. SAYLES: All right.

RICHARD GERING, Ph.D., PLAINTIFFS' WITNESS, SWORN

DIRECT EXAMINATION (CONTINUED)

BY MR. SAYLES:

Q. Mr. Gering -- Dr. Gering -- excuse me -- I want to go back to lost profits for just a moment.

You were here when Rob Bazemore testified before the jury.

A. I was.

Q. And in fact, is Rob Bazemore one of the individuals that you had an opportunity to interview as you were doing your work?

A. Yes. I met with him near the beginning of my work and also near the end.

Q. And you heard Mr. Bazemore discuss various competitors and the various indications for these drugs.

A. I did.

Q. And did you review documents in connection with those various competitors?

A. Yes, I did, both Abbott and Centocor documents.

Q. And in calculating the lost profits that you've given your opinion on to the jury, did you account for all the non-infringing alternatives that have been identified?

A. Yes, I did.

Q. Now, let's turn our attention to a reasonable royalty analysis, which you mentioned briefly to the jury earlier. And I think you mentioned the term hypothetical negotiation. Would you explain what that is, please.

A. Yes. A hypothetical negotiation is -- it's called hypothetical, because it didn't actually occur. It's a negotiation of what we -- what we're looking at is a negotiation that should have occurred or would have occurred between Abbott, who's the licensee seeking a license, and Centocor, who's the licensor, who has the patent.

And the object of the hypothetical negotiation is to understand both parties' positions and the data and to determine what a licensee, what Abbott would have paid Centocor to use the '775 patent so they could make and sell Humira.

Q. Was the hypothetical negotiation idea your idea, or is that the framework that experts, such as yourself, use in patent cases throughout the United States district courts?

A. It's the framework that patent experts use. There's a case called Georgia-Pacific that enumerates 15 factors, and typically, experts in this field look at those factors and do their analysis in the framework of those factors.

Q. As a part of your work, did you form a professional opinion as to a reasonable royalty rate that Abbott and Centocor would have agreed to in this hypothetical negotiation?

A. Yes, I did. In my opinion, the rate was -- that I determined was 15 percent.

Q. And in determining that, as we go deeper into it, did you make some assumptions?

A. Yes, I did. I made four main assumptions, and I have a slide that lists those assumptions.

Firstly, I'm assuming that the -- that there was what's called a willing licensor and a willing licensee at this hypothetical negotiation. So both Abbott and Centocor are at the table negotiating. Then I assume that the patent, the '775 patent, is valid and that Humira infringes that patent.

I also assume that the negotiation takes place in July, July 4th, 2006. That's the start of the period of infringement.

And lastly, I assume that both parties, Abbott and Centocor, have the relevant information necessary at this negotiation.

Q. Now, you've mentioned these assumptions. Are these assumptions you came up with, or are these assumptions that the law requires in an analysis of this type?

A. These are standard assumptions that one needs to make in order to do this analysis.

Q. You mentioned Georgia-Pacific. Just tell the

Ladies and Gentlemen of the jury briefly what we're talking about when someone refers to the Georgia-Pacific factors.

A. So there are 15 factors. This slide puts the 15 factors up. And I'm clearly not going to read this slide, but let me just talk in general terms.

It talks about the types of factors that a licensor and a licensee would consider and look at in both a hypothetical negotiation and a real negotiation.

So, for example, the first two factors deal with, are there agreements out there that either of the parties have been party to or that are agreements that relate to the patent-in-suit?

Factor 4 and 5, for example, relate to, does Centocor have a licensing policy, and are Centocor and Abbott -- are they competitors?

You also clearly need to look at things like profitability. So Factors 8, 12, and 13 deal with the profitability of the product, again, from both sides, Abbott, as well as Centocor.

And Factors 9 and 10, for example, deal with how important the product is.

So those are the kinds of things that you consider. What I do want to do is just highlight the last factor.

Q. All right. Now, before you -- we go to that, let me just ask you before we reach it, in doing your work before coming to Court and in arriving at your opinions, did you consider each and every one of these factors in detail?

A. I did.

Q. All right. Now, is there one particular factor that it would be helpful to the jury to talk about?

A. I think it would. Factor 15.

Q. All right. Would you please explain it.

A. Sure. Factor 15 in my mind really summarizes the negotiation. So it's the amount that a licensor -- that's Centocor -- and a licensee -- in this case, that's Abbott -- would have agreed upon, again, in July of '06, if both had been reasonably and voluntarily trying to reach an agreement.

So that's the amount that a prudent licensee -- that's Abbott. So how much Abbott, who desired, as a business proposition, to obtain a license to make and sell, in this case, Humira, using the '775 patent, how much would they have been willing to pay Centocor and yet be able to maintain some kind of a reasonable profit?

And it also looks on the other side of the

ledger of the amount that would have been acceptable by a prudent patentee -- that would be Centocor -- who was willing to grant a license.

So, again, the licensor has to be willing to grant a license. So, again, you have to look at it from both sides.

Q. Are you able to boil all of this down to several key questions that one should look at to make a determination of a reasonable royalty?

A. Yes, I am.

Q. All right. And would you explain to us what those are, please.

A. So I boiled it down to three questions.

One is, how important is the patent to the licensor, to Centocor, Johnson & Johnson?

The second question is, how important is this patent to the licensee? In this case, Abbott.

And then the last question is really looking at, are there other data points, are there other reference points or licenses that assist us in coming up at a number?

So, again, my analysis tries to look at both sides of the negotiation table, what Abbott would be willing to pay and what Centocor, J&J, would request, would demand to be paid.

Q. In analyzing this, did you make a determination of how important the patent was to the licensor, in this case, Centocor?

A. Yes, I did.

Q. Explain that.

A. And it's very important to Centocor, and I have a slide that sort of summarizes some of the main reasons.

We've heard a lot over the last two days about how important these drugs are and how they compete. So Centocor and Abbott are directly competing in this biologic market. And that's a very important factor to license a competitor.

At the time of the negotiation, Remicade is on the market. Remicade is selling very well. In fact, through today, Remicade has sold approximately $16 billion dollars in sales.

But more importantly, at the negotiating table in 2006, Centocor still had an expectation that Remicade would sell a tremendous amount more, $23 billion.

So licensing a competitor, when you have a product that's that profitable and that big is a very big deal. It's not only an important product to Centocor; it's Johnson & Johnson's largest product at this point in time, and it was Johnson & Johnson's --

one of its largest products in '06.

And, again, not just a hard product, but with an expectation to continue to grow. So it was very important to Centocor.

Q. Would you explain your opinion and analysis on the importance to Abbott?

A. Well, I have a slide also that summarizes that. And in my opinion, this license was also incredibly important to Abbott.

In 2006, at the time of the hypothetical negotiation, Abbott had forecasted that it would sell approximately $23 billion of Humira, the time period from '06 through 2011.

2011 is an important point, because that would be the end of the license agreement. Again, you don't have a license agreement forever. It has an end point. Abbott has no design-around to the '775 patent. That's important, because that means that Abbott, in this hypothetical world, could not just get up from the table and say to Centocor, I'm not willing to pay this, because I have an alternative. I can make the product in another way. I can sell Humira without infringing the patent.

This product was very important profitability-wise to Abbott. The gross profit on this

product is about 80 percent.

The annual report in 2007 says that by 2007, Humira became Abbott's most successful product in our history. It says it was not only an important product; it was the largest product in Abbott's entire history of more than a hundred years.

And in another document in that same timeframe, it says Humira is key to the former products group's current and future success. So Humira accounted for about 20 percent of Abbott's pharmaceutical sales.

So this is a very important product, a very profitable product. It's growing in size, growing in importance. And, again, Abbott did not have a design-around, so it's very important to Abbott.

Q. And what does all this add up to in your royalty analysis?

A. Well, at the negotiation table, it would drive the reasonable royalty up, because Abbott would seek and would need that license.

Q. One of the key questions you showed us a few minutes ago was an analysis or looking at license agreements and other data points.

Did you do that?

A. I did.

Q. Can you summarize for us what you looked at in

that regard, please.

A. Yes. I broke it down into, basically, five areas.

There are license agreements that Centocor has on Remicade with other parties that are not in this litigation, and there are license agreements that Abbott has dealing with Humira with parties, again, that are not in this litigation. So I looked at those.

There is also an agreement between Centocor and Abbott. We heard it a little bit earlier on today, the agreement involved in the Kennedy Institute. And there were various other agreements between other parts of Johnson & Johnson -- not Centocor, between other parts of Johnson & Johnson and Abbott that I looked at.

And lastly, I looked at some benchmarks and industry surveys and averages to help give me a benchmark as to what an appropriate rate would be.

Q. All right. Could you summarize for the jury what your review and analysis of the Remicade and Humira license reveals?

A. Yes. There are about five or six licenses that Centocor has with other parties and a similar number, five or six, that Abbott has with other parties, and those rates on those license agreements range

between about 0.3 percent and about 6 percent.

For example, the agreement between New York University and Centocor is about 4-1/2 percent.

So I looked at those agreements.

Q. Did these agreements establish a reasonable royalty in a hypothetical negotiation?

A. No, they did not.

Q. Why not? Explain that, please.

A. The agreements were signed at times when the economic conditions between the parties were different. So, for example, two major differences are that those are agreements where a licensor, either Abbott or Centocor, and the licensee -- so, for example, Centocor and NYU, NYU would be the licensee.

So these are agreements where the licensor and the licensee were not competitors. They were not competing directly. They were typically agreements with educational institutions or research institutions, as opposed to companies, such as Abbott and Centocor, that were competing.

So that was one major reason.

The other reason is that these agreements were typically signed two or three years before either Remicade or Humira had been approved by the FDA and become a commercial product.

And as we know, it can take -- there's risk and uncertainty. It can take time; it can take tens of hundreds of millions of dollars; and you can get almost all of the way through to FDA approval and the product may not be approved.

So at the time of signing an agreement, when a product is still in development, you typically see much lower rates because of that risk and uncertainty.

So for those reasons, I thought they were -- I looked at them, but they didn't -- they didn't, by themselves, establish a rate for me.

Q. Abbott and Centocor are competitors, and based on your knowledge and experience, what effect does that have on a royalty negotiation?

A. That, again, would typically drive the rate up.

Q. And in this case, we know that the product, Humira, was already on the market when the patent-in-suit issued. What effect does that have on a royalty negotiation in your experience and in your opinion?

A. Again, that would drive the rate up, because there's not the uncertainty that the licensed product may not get to a commercial stage.

At this point, you actually have a commercial

product that's doing very well in sales and profitability, and the expectations in those is that it will continue to do very well.

And indeed, not only was that an expectation, but it actually happened. Humira is -- last year sold $4-1/2 billion worldwide. So it's a very successful product.

Q. Now, you mentioned one of the categories of license agreements was between the parties. Have you analyzed and reviewed a license agreement between J&J, Centocor, on the one hand, and Abbott on the other hand?

A. Yes, I have. It's actually --

Q. Summarize that, please.

A. It's actually two agreements. I believe Mr. Dow spoke about them this morning, and that's related to the Kennedy Institute. And I believe I have a slide that summarizes those.

Q. All right. And in evidence, those agreements are Plaintiffs' Exhibit 121 and Plaintiffs' Exhibit 669. And you've reviewed those, haven't you?

A. Yes, I have.

Q. And could you summarize that for us, please.

A. And, again, I looked at those two agreements together. They were signed at the same time. They're between the same parties, and in fact, they reference

each other.

So on the one hand, Centocor grants Abbott a sublicense for Humira co-administered with Methotrexate. So that's when Humira is used with, administered with Methotrexate.

So Centocor did allow its competitor, Abbott, to go into a competing product by giving them that license, and that's in December of 2002. But in return, Centocor got something in return.

So Abbott pays to -- for the right to sell Humira co-administered with Methotrexate. And, again, that's not in the entire market; it's in a limited market, not -- so it's not all Humira.

Abbott pays a royalty of 2 percent to the Kennedy Institute, as well as Abbott granted Centocor rights to certain technology that was related to -- and at that time, it was called CNTO, C-N-T-O, 148.

At a later point in time, the document's calling it golimumab, and this is the product they just launched in April called Simponi.

Q. All right. And you mentioned this product, and how did you determine its value was in the context of these negotiations between the parties that resulted in a license going one way and a license coming the other?

A. There were documents that showed that Centocor valued the CNTO-148 or Simponi product, that they valued that product extremely highly. There are sales projections at the time of the hypothetical negotiation; there are sales projections at a later point in time. So it was an incredibly valuable product to Centocor.

So what you see on the slide is, in 2003, the sales projections. So the negotiations in December of 2002 -- and I'm talking about data from a 2003 strategic plan, and the way that these strategic plans work is that they are developed at the end of the year prior. So they are developed at the end of 2002.

And Centocor projected sales of CNTO-148 at that time to be about $1.9 billion over the time period of 2008 through 2012.

So in 2002, they expected the product to launch in '08. It actually launches in April of' 09. But they thought this was a very valuable technology. I looked also at the data point at 2006. And 2006 is important to me, because the hypothetical negotiation is in July of 2006.

So by July of 2006, in their strategic plan, Centocor had upgraded its forecast of sales of what becomes Simponi to approximately $5.6 billion. They realized at that point that the product will launch in

'09, and again, it's a five-year forecast up to 2013.

So, yes, they licensed Humira to get on the market, but they got something that they thought was extremely valuable in return. And that information would be key at the hypothetical negotiation.

Doesn't tell us specifically what the royalty rate is but it does tell us that Centocor would want something of extreme value in return to allow Abbott on to the rest of the market.

Q. Now, let me see if I understand correctly.

This data point, as you call it, in 2003 was developed in 2002 relating to Simponi.

A. Yes.

Q. Seven years before it actually got to the market.

A. Correct.

Q. And is that unusual in the pharmaceutical industry?

A. No. It's not unusual for a product to take a long time to get through development to be launched. But during that time period, a company's spending a tremendous amount of money and resources to try and get that product through development and to launch.

And so it's not unusual for the financial and marketing people to have projections of what they expect

the product to do, assuming that it will be launched. Otherwise, why would you -- how would you explain to management that it was reasonable to spend hundreds of millions of dollars? You have to have an expectation that you would recoup that money.

Q. So in context, what you're talking about is a license agreement that Centocor obtained from Abbott in 2002 for a product that it had very high hopes for at some point in the future?

A. Correct.

Q. Now, have you seen any documents from Abbott that have any suggestion or indication about what they thought the value of the rights that were being conveyed to Centocor back in 2002?

A. Yes, I have. I've seen a document from Abbott that values those rights in the Abbott document at $1.6 billion.

Q. All right. Let's take a look at Exhibit 465, please. Is this the exhibit?

A. I think that's my CV. I don't think that's it.

Q. That's 466.

A. That is -- that's the first page of the exhibit. I believe the last page is where the information is, and it's --

Q. Let's look at the first page, okay?

A. Okay.

Q. This is -- as you understand it, this is an internal e-mail that we were able to obtain in this case from Abbott.

A. Correct.

Q. And in September of 2005, and one Abbott person is communicating with another.

A. That is correct.

Q. All right. Now let's go to that page.

A. Okay. So there's clearly a lot of information on the page, and what was important to me was the fifth and the sixth bullet point.

So the fifth bullet point is that J&J claimed, when Abbott needed a license to the Kennedy patent at the time of the Humira launch -- that's what we're talking about in December of 2002; we just talked about that concept -- J&J had provided it to Abbott for only a pass-through consideration.

So J&J -- this bullet point talks about J&J had allowed or Centocor had allowed Abbott on to the market to sell Humira co-administered with Methotrexate and that there was a 2 percent royalty, but that 2 percent royalty went to Kennedy, not to Centocor. So that's the context.

The next bullet point explains what the Abbott person is writing. It says J&J failed to recall that they received in exchange for a license to the Kennedy patent -- and what they received was a license to the Salfeld human TNF patent, the '382 patent. And so that's dealing with the other half of those two agreements.

And then they say, We, Abbott, have estimated that J&J derived 1.6 billion in value. And then it explains in parentheses what it means by that. It says NPV of margin for CNTO-148.

So what that means to me is -- NPV typically means net present value. So, again, these are going to be sales going out into the future. The net present value says, what is that future benefit worth in a lump sum today? So today would be September '05.

And it's of margin. Margin is another word for profit as opposed to for sales. So it has a present-day value of profit of 1.6 billion according to the Abbott person.

And, again, that's for CNTO-148, and CNTO-148 is the product that gets named Simponi when it goes to the market.

Q. So in looking at those license agreements, is it fair to just focus on the number for a royalty there?

A. No, it's not.

Q. You mentioned that there were some agreements between Abbott, on the one hand, and other parts of Johnson & Johnson that you evaluated and considered.

Could you briefly summarize that for us, please.

A. Yes. I saw a number of agreements. There were some ranging from about 4 percent to about 12 percent, which I looked at, but I didn't consider to be directly comparable.

And then there was one agreement that I thought was directly comparable that I used in my analysis.

Q. And just to get us started here, what agreement was that?

A. That was an agreement between Cordis, which is another part of Johnson & Johnson, and Abbott, and that was an agreement that related to stents, stents on medical devices that are used for arterial blockages.

Q. Now, is Cordis a Johnson & Johnson subsidiary as Centocor is a Johnson & Johnson subsidiary?

A. Yes, it is.

Q. And you understand that we're not addressing stents in this case, don't you?

A. I do. We are dealing with biological

products.

Q. And from an economic standpoint, can you tell us why you consider that important to consider in the context of our case?

A. I can.

The first reason is that in this case, this part of J&J Cordis and Abbott were direct competitors. They were competing in a market where these stent products typically sell on the order of a few hundred million dollars a year. So it's a very big market. It's a very profitable market. It's a very growing market.

There was also at a time -- this negotiation was at a time when my understanding is that Abbott needed a license in order to commercially launch its products. Its products were ready or about to be ready, but it needed a license. These patents were blocking patents, so Abbott needed to take a license.

Abbott approached J&J and sought a license, and J&J granted a license. And so I thought that from an economic perspective, there was a lot of comparability.

Q. Under those economic facts, what type of royalties are reflected in that agreement?

A. There were three royalties.

There was a royalty of 26 percent for what was called the Palmaz patents, which my understanding were the most important patents in this agreement, there was a royalty of 15 percent, and there was a royalty of 3 percent for two other sets of technology that were less important.

Q. Now, Dr. Gering, you're not advocating a 26 percent royalty in this case, are you?

A. No, I'm not.

Q. And I want you to be sure and explain to us why this agreement is relevant, relating to stents with a 26 percent royalty, to the extent that you haven't already.

A. I thought it was important because, again, when dealing with competitors with important products that are on the market dealing with a patent that was necessary for the licensee to have -- without that patent, they couldn't sell the product that they wished to -- and it shows that in those types of conditions, you can easily get royalty rates of above 20 percent. And so I thought that was an important consideration in my analysis of what the licensee would have known and the licensor would have known, because here was an agreement, a real agreement, between the two parties.

Q. You mentioned another data point, and I want

to move to that. You mentioned the studies or information available in an industry.

A. Yes, I did.

Q. And in this case, were you able to find some -- such information?

A. Yes, I was.

Q. I would like to show you Plaintiffs' Exhibit 464 in evidence, and let's start with the cover.

Tell the Ladies and Gentlemen what this is.

A. This is a biopharmaceutical royalty rates and deal terms report. It was published and -- the study was commissioned by and then published by the Licensing Executive Society in June of '08.

And it relates to information collected by survey from deals done in '05, '06, and '07. They looked at a couple of hundred deals under different -- segmented in different -- different ways.

Q. This License Executive Society is one to which you belong?

A. I do.

Q. Let's look at Page 1, the introductory letter in the first paragraph there.

MR. SAYLES: If I could have that highlighted, please. Just the first paragraph, please.

A. Well, this is a study that was done, because

the organization's objective was to provide its members with relevant licensing information. It was -- there's -- later on, it says it was to be used or potentially used as a benchmark so that licensing executives can use it.

And it was basically based on surveys of people that are already involved in the industry. It was targeted at people in the pharmaceutical and the biotech industries, so they talked to people in academic institutions and in pharmaceutical and biotech companies, community both licensors and licensees, to get and accumulate the information.

Q. (By Mr. Sayles) I have a two-sided copy of the exhibit here in my hand. Have you reviewed the entire report?

A. At one point, I read it. I wouldn't say I've memorized it.

Q. All right. Let's go to Page 3, and I'd like you, if you would, to tell the Ladies and Gentlemen of the jury about this study before we go to the particular part that we want to focus on.

Start with the first paragraph.

A. So the LE -- it talks about what the LES is. It's 6,000 members who engaged in dealing with intellectual property, the manufacturing, the

transferring, the licensing.

Typically, people are either licensing professionals at pharmaceutical companies or high-tech companies, consultants, lawyers, academics.

And this was a survey of people in the biotech and pharmaceutical sector -- you see in the second paragraph -- in an attempt to benchmark important areas of deal-making for licensing professionals.

This was an update of a study that was done in 1992. The LES and members of the LES felt that updated information would be useful. So it was -- again, it was conducted on data in '05, '06, and '07, and it was published in the middle of '08.

Q. All right. And just briefly look at the next paragraph and tell us its importance.

A. Its importance to me is the highlighted section, that it's a benchmark of important areas of deal-making.

Q. All right. Let's go down to the fourth paragraph regarding the LES survey, and tell us who it is directed to or at.

A. Well, again, what shows in the fourth paragraph is that it's an update of a survey done in 1992, and clearly, the author's hope, that the report is useful to LES members and others who are interested in

the field of licensing and intellectual management, intellectual asset management.

Q. All right. I would like you to take a look just very briefly at Page 6.

You indicated that this data was collected over the previous three years. That's shown in the first paragraph.

A. Yes. This -- well, it goes through, I guess, how it was collected. The LES asked an outside organization called Veris -- they targeted various individuals and companies. They sent survey information, follow-up information.

I think in the end, they had 230 or 233 respondents, and from that, they had complete data on about 100 or 150 licenses.

Q. All right. Right above that, the sentence in the paragraph above it that ends that paragraph, in order to garner?

A. In order to garner further participation, the LES royalty rate committee -- that's the office -- personally contacted the top 50 pharmaceutical companies.

So it was -- definitely, it was an attempt to get live, real data. And one of the ways they did it is that though they've summarized all the information in

the report, you don't have any names.

So people provided information, but they -- but they don't release -- in the study, they don't release the actual names of agreements between who the companies were. They've just summarized it.

Otherwise, nobody would really give them confidential information.

Q. Based on your knowledge, is Centocor in the top 50 pharmaceutical companies?

A. I know J&J is. I'm not sure if Centocor is measured separately. But J&J is definitely in the top 10.

Q. Is Abbott in the top 50 pharmaceutical companies?

A. Absolutely.

Q. All right. Now, is there a particular page of this Licensing Executive Society that you think would be helpful to the jury in understanding your opinions?

A. Yes, I do. There's a -- there's a page related to royalty rates at launch. I think it's Page 27.

Q. All right.

MR. SAYLES: Let's go to Slide 5.

A. Page 26. So this is a page from the report, and it talks about fixed royalties or average royalties

by stage of development.

Fixed royalty just means that the royalty rate is the same number over the life of the agreement as opposed to changing.

And what's important to me is this bar chart. And there are three -- there are three bars there. The one that's highlighted is -- it's called Group 5 launched.

And what that means is that's the average royalty rate in these agreements between licensors and licensees where a product is actually launched. It's commercial. It's not a -- it's not something in development.

So that gives a benchmark of 11.6 percent from the study.

I thought what was also interesting are the two little bars on the left, Group 1 and Group 2. Group 1 is called preclinical, and Group 2 is called pre-POC.

So preclinical is typically at a very early stage in development, around what's called Phase 1 or Phase 2. So that could be a number of years before a product launches, maybe five or six years even. And pre-POC is typically between Phase 2 and Phase 3 of the clinical studies as defined by this report.

So that's further on in the development stage but still maybe a year or two or three away from actually getting an FDA-approved product.

And what you notice is, those numbers are less than half of the 11.6. So it shows that when you're licensing something before it's launched, that risk and uncertainty is reflected in the royalty rate compared to when you're licensing something that's actually a commercial product.

Q. (By Mr. Sayles) Now, based on this work that we've talked about, in looking at some of these data points we've talked about, I just want to ask you, did you look at a whole lot more?

A. I did. I looked at other rates --

Q. All right.

A. -- and other surveys.

Q. And is what we've talked about here a fair representative summary of the types of data and information you've studied and analyzed before coming to Court?

A. I believe so.

Q. And do you have an opinion as to the reasonable royalty rate of 15 percent and a basis for that?

A. I do.

Q. And I would like to show you a calculation of the reasonable royalty, and I'll ask you if this is your calculation.

A. Yes, it is.

Q. And would you explain to the Ladies and Gentlemen of the jury how you made this calculation so that they will understand your opinion.

A. So what you see there is a reasonable royalty of 15 percent, and the line above it is total Humira sales subject to the royalty of approximately 6.7 billion. So that was the slice in the pie that we saw earlier on.

And that's made up of two numbers. It's sales in the United States of infringing Humira that are not in the lost profits calculation and then the sales of Humira outside of the United States.

And if you multiply the 6.7 billion number by the 15 percent, then the royalty damages are 1,008,256,000.

Q. And in terms of the royalty base, did your numbers come from the data that has been exchanged in this case --

A. Absolutely.

Q. -- and the exhibits admitted in evidence?

A. Yes.

Q. Did you analyze the impact, if you will, of a 15 percent royalty on Abbott's profits for Humira?

A. I did.

Q. Would you explain that, please.

A. Yes. I have a slide that shows both why I think the number is reasonable and what the profits are at the end.

So, again, I looked at, again, royalty pays on -- paid on Remicade and Humira. There was a range, .3 to 6. 4-1/2, for example, was the NYU agreement. And I didn't think that they were directly comparable because they weren't competitors. This was before launch. And so the rates could double.

Then I looked at the industry averages, which was 11.6.

Then I considered the fact of what Centocor got in return for letting Humira on the market administered with Methotrexate. And that was valued at $1.6 billion by Abbott.

I also looked at what I thought was an economically comparable agreement with Abbott.

And then I looked at some other factors that they -- the competitors, which the arrow shows that it drives the rate up. Humira is very profitable, it's very important to Abbott, and it's of growing

importance.

And then lastly, there's no design-around.

So I thought my 15 percent rate was reasonable and supportable.

And then I looked at what its impact was on Abbott's profit. So the next slide would show the impact on the profit.

And after paying a 15 percent royalty to Centocor, Abbott is left with a profit of $32 on every hundred dollars of sales.

So if they pay the 15 percent and then they pay all the other costs, the cost of making the product, the cost of promoting the product, the cost of selling the product, as well as the other licenses that it pays to third parties not in this litigation, as well as continued studies, so all those other costs, they're still left with $32.

Q. Did you prepare a slide to summarize your calculations of damages combining lost profits and a reasonable royalty?

A. I did.

Q. And could we look at that, and does this reflect your opinion as to both the reasonable royalty and the lost profits sustained in this case?

A. Yes. The yellow bar there shows the sum of

the total lost profits by the different indications. And then the line below shows the reasonable royalty on the sales that are not included in the line above. And then the total is 2.176 billion.

Q. All right. I want to go through these numbers, because we are creating a record here, and this is to aid the jury.

A. Okay.

Q. So what was the total lost profits in your opinion that were sustained in this case?

A. $1,168,466,000.

Q. And what would be a reasonable royalty not including any sales including -- included in lost profits already in your opinion?

A. So the remaining sales that are not in the lost profits, the royalty would be 1,008,256,000. And then the two combined would be 2,176,722,000.

Q. All right. Now, at my request, did you do some other calculations?

A. Yes, I did.

Q. Did you calculate lost profits assuming no lost profits in rheumatoid arthritis?

A. Yes, I did.

Q. And have you prepared a summary of that?

A. I did.

Q. And would you explain that to the ladies and gentlemen of the jury if you have no lost profits for rheumatoid arthritis?

A. So you can see in the top line, the lost profits in RA is now zeroed out. It's now a zero. So there's no lost profits under this scenario.

And then the total lost profits and reasonable royalty number would become 1,673,752,000.

Q. And at my request, did you do a calculation of the damages assuming only lost profits for Crohn's disease?

A. I did.

Q. And do you have a summary of that that you could explain, please?

A. Yes, I do.

So what you see here on this slide, there are only lost profits for CD, for Crohn's disease. So RA, AS, PsA, and PS are all zeros in that top part of the slide. And then the total damages combination of lost profits in Crohn's disease, plus reasonable royalty would be 1,494,912,000.

Q. These last two calculations you did at my direction and request.

A. Yes.

Q. What is your first solid professional opinion

as to the damages in this case?

A. It would be the next slide, which would be lost profits in all of the therapeutic areas in the United States so that the total number would be 2,176,722,000.

Q. Did you take into account the arbitrator's award and not include sales for the drug that was combined with Humira that was combined with Methotrexate?

A. I -- I accounted for it by removing it. It doesn't exist in my damage calculation.

MR. SAYLES: I'll pass the witness.

MR. BECK: May it please the Court.

CROSS-EXAMINATION

BY MR. BECK:

Q. Good afternoon, Dr. Gering.

A. Good afternoon.

Q. You and I have never met before, have we?

A. I don't believe we have, sir.

Q. And just so we're clear, I'm on the other side from you. You know that, don't you?

A. Yes, I do.

Q. And you know I'm going to ask you some questions about some of these numbers and calculations that you just got through telling the ladies and

gentlemen of the jury about.

A. Yes, I do.

Q. All right. Now, you told the ladies and gentlemen of the jury that you were involved in about a hundred other patent cases; is that correct?

A. Yes.

Q. And in those approximately 100 other patent cases, you testified, did you not, in a lot of them?

A. Not in all of them, but in many of them, yes.

Q. And you've given depositions in a lot of those cases, have you?

A. Correct.

Q. You've testified in a court of law in some cases?

A. Correct.

Q. So you are an experienced testifier, are you not?

A. I have experience, yes.

Q. You've even testified for and on behalf of Johnson & Johnson in other cases, have you not?

A. Correct.

Q. Now, you have told the ladies and gentlemen of the jury that as an expert, you have made certain assumptions, correct?

A. Yes.

Q. And that's perfectly proper; nothing wrong with that. It's just something that an expert must do in order to get to the bottom line.

A. Absolutely.

Q. And in your particular case, you, for example, assumed that there was infringement of the '775 patent.

A. That is correct.

Q. Don't know that, do you?

A. I don't know it at all.

Q. Not giving an opinion that we infringed that patent.

A. Not at all.

Q. Not suggesting to the jury, top side or bottom, we infringe that patent, are you?

A. No, I'm not suggesting anything.

Q. You're also not suggesting to the ladies and gentlemen of the jury that somehow this '775 patent is valid, are you?

A. Correct. I'm not suggesting that.

Q. Not suggesting, top side or bottom, that that patent is valid.

A. I have no opinion on that.

Q. What you've done, because you were told to do that by the lawyers representing the other side -- and that's entirely proper -- Doctor, I want you to assume

that this patent is infringed, and I want you to assume it's invalid -- excuse me -- is valid, correct?

A. That is correct.

Q. Now, if the ladies and gentlemen of the jury, who must decide whether or not this patent is infringed or not -- you understand they're going to make that decision.

A. Absolutely.

Q. If they decide that this patent is not infringed, then despite all these slides we've seen, all these calculations you have done, the damages are zero, are they not?

A. That is correct.

Q. And if the ladies and gentlemen of the jury, in their infinite and collective wisdom, decide that the '775 patent is invalid, then despite all these slides we've seen, all these calculations we've seen, the answer to the damage issue is zero, correct?

A. Yeah. My number is zero, yes.

Q. All right. Now, a couple of questions, and I tell you, Mr. Lee told me to ask these, and I don't know why I'm asking them, but I'm going to ask them anyway.

You're not a scientist, are you?

A. That is correct.

Q. And you never have made an anti-TNF antibody

of any kind, correct?

A. That is correct.

Q. And you talked about this arbitration. You know, do you not, sir, that that arbitrator never decide -- decided whether or not the '775 patent was infringed or not, did he?

A. That's my understanding, yes.

Q. The issue was not before him, was it?

A. I -- I don't believe so.

Q. Okay.

A. I certainly have assumed such.

Q. All right. And the arbitrator did not decide validity --

A. That's my --

Q. -- of the '775 patent.

A. That's my understanding.

Q. And those are the issues this jury's going to decide, as you understand.

A. Absolutely.

Q. Now, you were asked a few minutes ago about whether or not you were asked to make some calculations by counsel for Centocor in this case, and it was Slide 30 and 31.

When were you asked to make those calculations?

A. Well, those calculations were already in my report in the sense that my report had very detailed numbers. I was asked to put those numbers out there without those -- with those adjustments a few weeks ago.

Q. All right. So the -- the calculations with these adjustments you've told the ladies and gentlemen of the jury about was after your report was prepared?

A. Well, can I give a slightly longer --

Q. Let me --

A. My report was updated last week because of updated data, so -- but it was after my initial report, yes.

Q. After your initial report is when those adjustments were made.

A. Correct. My initial report had those numbers in them, but I just zeroed them out. But they were in the calculations.

Q. And this was a couple of weeks ago?

A. Yes.

Q. Now, I want to clarify one point before I actually get into the -- a lot of the questions I want to ask you.

A. Okay.

Q. The $32 of profit that you say that our client, Abbott, makes for every $100 of sales, from the

work you've done in this case, you know, do you not, that that $32 has got to be used and will be used for research and development for other new drugs and medicines, don't you?

A. Well, some of it will be. Typically, some of -- some profits from pharmaceutical companies are reinvested for more research and development, yes.

Q. And you've seen in some of the work you've done in this case that a very, very small percentage -- not just for my client, but for Centocor as well -- are unsuccessful (sic) for whatever reason. You know that.

A. I think you meant to say are successful, but I would agree with you. A very small percent are successful, depending when on the pipeline you're looking at it, absolutely.

Q. All right. Now, let me start with what you've actually done in terms of your fundamental opinions.

What you have done in this case, Doctor, as I understand it, is you have formed the opinion that an appropriate damages award in this case would be a combination of lost profits and a reasonable royalty?

A. Yes.

Q. Both.

A. Yes.

Q. And so let me start first with a reasonable

royalty. May I do that, please?

A. Absolutely.

Q. Now, a reasonable royalty analysis, so that I can understand it, involves trying to figure out what Abbott and Centocor would have done if they had sat down and negotiated a license.

A. Correct, back in -- back in July of 2006.

Q. Absolutely. Back on July 4, 2006.

A. Yes.

Q. And you selected July 4, 2006, because that's the date the patent was issued.

A. Yes. Yes.

Q. All right. Now, this is what is called a hypothetical negotiation, right?

A. Correct.

Q. We know there wasn't such a negotiation, so you, as an expert, and our expert has got to try to figure out, well, what would these two parties have done back on July 4, 2006, if they had sat down and tried to negotiate a license? That's what you're trying to do.

A. Correct.

Q. And your opinion was that if these two parties, Abbott and Centocor, had sat down on July 4th, 2006, they would have come up with a 15 percent royalty rate.

A. Yes.
Q. That's your opinion.
A. Yes.
Q. Now, one of the things you told us in Slide 19 was that one of the -- one of the steps that you go through in trying to reach an opinion with respect to what this reasonable royalty rate is going to be, you look for other licenses or reference points, don't you?
A. That is one of the -- one of the things that I looked at, yes.
Q. What has Abbott done in the past that's somehow comparable, right?
A. Well, it's two steps: What has Abbott done, and then what has Abbott done that is somewhat comparable, yes.
Q. Right. Same thing for Centocor.
A. Correct.
Q. And then you actually even look for other agreements by other parties, other than Centocor or Abbott, that you think might somehow be relevant --
A. Correct.
Q. -- right?
And then you look at those numbers, and then you consider all those numbers, and you try to come up with a number that you believe is a fair, a fair

reasonable royalty rate, correct?

A. That was my intention, yes.

Q. Now, so that the ladies and gentlemen of the jury might know, in -- this report you wrote is about that thick (indicating), isn't it, your original report?

A. Yes.

Q. Now, in that report, in the body of your report, you discussed as data points ten other agreements, didn't you? And I'm going to go through each one of them very quickly.

A. It sounds -- it sounds about right. I discussed some in the body of the report. I referenced a whole host of additional ones in an appendix. I looked at many agreements.

Q. No. I'm talking about the ones you actually went so far as to discuss in your report. There are ten of them, aren't there?

A. There are ten that I specifically mention in the body and by reference. All the other ones are mentioned in the body.

Q. All right. And of those ten agreements that are mentioned in the body, so that the jury might know, nine of those ten have a royalty rate lower than your 15 percent number you've come up with, right?

A. Yes.

Q. And some of those that are mentioned in the body of your report -- and I'm talking about these other nine -- some of those percentages were significantly lower than your 15 percent, weren't they?

A. Yes.

Q. Now, the one agreement that you've just spent a few moments talking to the jury about, that does have a rate that's either at or above your 15 percent is the Abbott/Cordis agreement, correct?

A. Yes.

Q. And Cordis is a J&J subsidiary, as you've told us, right?

A. Correct.

Q. That agreement has nothing to do with Humira, does it?

A. Correct.

Q. Has nothing to do with Remicade.

A. Correct.

Q. Has nothing to do with any anti-TNF antibody, does it?

A. Correct.

Q. In fact, it has nothing to do with any biologic, like Remicade or Humira, does it?

A. Correct. It's a medical device. It's not a drug.

Q. It has nothing to do with rheumatoid arthritis.

A. Correct.

Q. Didn't even involve a pharmaceutical product, did it?

A. Correct.

Q. As you've said, it involved a heart stent, which is a medical device, correct?

A. Yes.

Q. And you will agree, will you not, sir, that the technology involving heart stents is not comparable to technology involving TNF-alpha antibodies.

Would you agree with that?

A. The science is definitely different, if that's what you mean by the technology, absolutely.

Q. And in fact, the competitors in that market are totally different than the ones we're talking about in this courtroom, aren't they?

A. Correct. J&J and Abbott are the same, but then the other competitors are very different, yes.

Q. And when Abbott and Cordis entered into that agreement, Abbott didn't have any product on the market, did it?

A. My understanding is that they needed that license to launch their products. It was right at that

time. I'm not sure if they did or didn't have a product, but it was all contemporaneous, is my understanding.

Q. And when Cordis granted that license, they were allowing Abbott to get into a market that Abbott was not yet in; isn't that right?

A. That's my understanding.

Q. And wouldn't that have tended to cause the price to go up?

A. I don't believe so. I think it would cause it the other way.

Q. Well, you've got Cordis that's allowing a competitor to get into a market that it was not in before and to compete with it, right?

A. Yes.

Q. Now, another agreement you looked at in your -- the body of your report is called the Janssen-Abbott agreement.

You're familiar with that?

A. Yes. There may have been two of them, but yes.

Q. Well, one was a 1986 agreement.

A. I think so.

Q. And that agreement covers an anesthetic induction agent in Canada, right?

A. Yes.

Q. Not a biologic, like Humira or Remicade, was it?

A. Correct.

Q. Had nothing to do with rheumatoid arthritis or any of these diseases we've been talking about for the last two days in this courtroom, right?

A. Correct.

Q. There was no commercially available product on the market at the time this license was negotiated.

A. Correct.

Q. And the rates in that license were 6.25 percent up to 12.5 percent on net sales.

A. Yes.

Q. Then there's the 1989 Janssen-Abbott agreement.

You're familiar with that?

A. Yes.

Q. And that product covered an agreement that was really part of an automated drug delivery system, wasn't it?

A. Yes, it was.

Q. Not a biologic, like Humira or Remicade, was it?

A. Correct.

Q. Nothing to do with the diseases we've been talking about in this courtroom for the last couple of days, correct?

A. Correct.

Q. No commercially available and approved product at the time of that agreement.

A. Correct.

Q. And just so that the jury might know, that was the 1989 agreement, right?

A. Yes. December 29, '89.

Q. And the license rates in that agreement were 6 percent and 10 percent, weren't they, sir?

A. Yes, they were.

Q. And then there was another agreement in 2002 that you discussed in the body. That's the Abbott-Tibotec agreement, if I'm pronouncing that correctly, correct?

A. That's the way I pronounce it. We may both be wrong.

Q. All right. And in that agreement, Tibotec, if we're both pronouncing it correctly, gained the rights to co-promote Abbott's Ritonavir product with one of its own products.

A. Yes.

Q. And just so the jury might know, that product

is used to treat AIDS, isn't it?

A. That's my understanding.

Q. Good product?

A. I don't know one way or the other.

Q. In any event, the product is not a biologic like Humira or Remicade, is it?

A. Correct.

Q. It doesn't treat the diseases that we're talking about here?

A. Correct.

Q. And the product that Tibotec sought to co-promote with our product was not approved at the time of the agreement, was it?

A. Correct.

Q. And the royalty rate on that agreement for worldwide sales was just 10 percent, wasn't it?

A. Yes.

Q. There was another agreement that was referenced in the body of your report. That's the Amgen Ortho.

Now, Ortho, that's a subsidiary of Johnson & Johnson, isn't it?

A. Yes, it is.

Q. That's a 1985 agreement?

A. Correct.

Q. More than 20 years before the date of this hypothetical negotiation we've been talking about?

A. You're correct.

Q. Abbott was not a party to that agreement, right?

A. Correct.

Q. And the product covered under that agreement was really a hormone which controlled red blood cells.

A. Yes.

Q. Again, not a biologic like Humira or Remicade, was it?

A. Correct.

Q. And the royalty rate in that agreement was 10 percent, wasn't it?

A. Yes.

Q. Now, we've talked about Humira -- excuse me. We've talked about Abbott, and we've talked about Centocor.

You know, do you not, sir, that -- because you've looked at the documents, that there's actually four agreements, four licenses, that Abbott has entered into that actually do relate to Humira, correct?

A. Either four or five.

Q. All right.

A. I think one expired. But, yes, absolutely.

Q. So you've got Abbott, which is one of the parties to this hypothetical negotiation that's actually entered into a license agreement involving the very product that we've been talking about in this courtroom. Humira, correct?

A. Yes, it involves Humira.

MR. BECK: And can we bring up DX220, please?

And, specifically, I believe it's Page 11.

THE WITNESS: Is it a possibility -- that's better. The focus -- the screen is not great.

MR. BECK: We've tried to use copies so you could feel free to use the manual copy or the screen, whichever is more comfortable for you.

THE WITNESS: Great.

MR. BECK: Are you ready?

THE WITNESS: Yes, I'm fine.

Q. (By Mr. Beck) On Page 112.04 of this agreement talks about how the licensee shall pay to Abbott a royalty of 2 percent of all net sales, correct?

A. That's what it says, yes.

Q. So, basically, we have a license that Abbott is issuing, and the royalty is 2 percent.

And we're actually talking about Humira,

aren't we?

A. I believe -- could you tell me what tab it is in my binder? Sorry.

MR. BECK: Your Honor, may I approach --

THE COURT: Certainly.

MR. BECK: -- just to maybe help a little bit.

I'm sorry, Doctor. I thought we had them all tabbed. There you go.

THE WITNESS: Great. Thank you.

MR. BECK: Okay?

THE WITNESS: Thanks. Sorry about that.

Q. (By Mr. Beck) Okay. And you see it's actually 2 percent; is that not correct?

A. That is correct.

Q. And does it involve Humira?

A. It does. And I think I spoke about this agreement in my direct.

Yes, it does involve Humira.

Q. Now, I'm going to try to short-circuit this for confidentiality reasons. You had access to documents that are very, very confidential, because we're competitors in this courtroom.

You understand that?

A. Yes, I do.

Q. And there's certain information that you've had access to that even Centocor does not have access to.

A. That is correct.

Q. And our expert has similar arrangements.

A. I understand that, yes.

Q. So there are three exhibits; one is DX552, which is in your notebook.

A. Okay.

MR. BECK: And, Your Honor, I would like to refer to these without specifically identifying the company for confidentiality reasons.

THE COURT: Well, your operator needs to keep them off the screen. He just popped that one up there.

MR. BECK: Let's not put it up on the screen.

Q. (By Mr. Beck) If you can just get the -- do you have the agreement there?

A. Yes, I do.

Q. I'll ask you to look at DX552, and let's not put it up on the screen.

THE COURT: Just a minute, Mr. Beck. Ladies and Gentlemen, you'll have access to these exhibits should you want to see them in the jury room.

The numbers might be important to you. If they are important, I'm not saying they are or not. I just wanted you to know that they will not be withheld from you for confidentiality reasons.

Go ahead.

Q. (By Mr. Beck) Just looking at DX552, without identifying the companies on there, that is a patent license agreement, is it not?

A. I believe it is. I think it's for manufacturing, but it relates to some patents, yes.

Q. And it involves Abbott, does it not?

A. It does.

Q. And if you look at Page 7 of that exhibit and specifically 3.3.

A. Okay. I have it.

Q. And it talks about the royalties.

A. Yes, it does.

Q. And if you'll look at the last sentence in that first paragraph, if you'll just read that for the Ladies and Gentlemen of the jury, please.

A. The royalty rates on net sales attributable to a given licensed product in a given country or sales shall be 0.35 percent with each patent family involved in its manufacturing, use, or sale up to a maximum of 1.05 percent.

Q. So the royalty range there is .35 up to 1.05.
A. Correct. And I think I referenced that also in my direct.
Absolutely. I agree.
Q. Far different than 15 percent, isn't it?
A. Yes.
Q. And if you will also look at DX553.
MR. BECK: And please don't put it up on the screen.
A. Okay.
Q. (By Mr. Beck) It should be right behind that one, Doctor.
A. It is. I have it.
Q. Again, this is a license agreement, is it not?
A. Yes, it is.
Q. And if you will look at Page 4.
A. Okay. I have it.
Q. It specifically talks about the ongoing royalty, does it not?
A. Yes, it does.
Q. And the ongoing royalty range is from 3 percent to 4-1/2 percent and as low as 1-1/2 percent, correct?
A. Yes, I think so. It seems to say that there is a 3 and then there's a 1-1/2. So it could be 4-1/2.

And then there were other conditions, so yes.

Q. All right. And let's look at DX555.

A. Okay. I have that.

Q. And, again, without identifying the company, that is a license agreement -- it's an agreement dated October 25, 2005, is it not?

A. Yes, it is.

Q. Involves Abbott.

A. It does.

Q. And if you will look at Page 6 of that agreement, specifically Paragraph 3.9.

Tell the jury what that royalty rate in that agreement is.

A. This is the agreement -- a settlement of a prior litigation, and the rate that they settled on is 2.688 percent, called the Humira running royalty rate.

Q. So to sum up, in looking at DX220, DX552, DX553, and DX555, we see that the royalty rates mentioned there are as low as .35 percent and as high as 4.5 percent, correct?

A. Correct. I would say that they go up to 6 percent, because the last agreement that we talked about originally was a 6-percent agreement. The 2.68 was a settlement.

But, absolutely, I agree with you.

Q. Fair enough.

Now, let's talk about another agreement.

A. Okay.

Q. In this hypothetical negotiation between Centocor and Abbott, there is actually an agreement, a sublicense between Centocor and Abbott, the two parties to this hypothetical negotiation we're trying to work through, correct?

A. Yes, there is.

Q. And not only was that license agreement between the parties to this litigation, but it also covered Humira, did it not?

A. Yes, it did.

Q. And this license agreement was signed right around the time that Abbott launched Humira?

A. Correct. December of '02. And I think the launch was January of '03, so right around that time.

Q. And by executing this license, Abbott was letting a competitor, Centocor, into the market, was it not?

A. Centocor was letting a --

Q. Excuse me.

A. -- competitor, Abbott, into the market. Yes, absolutely.

Q. I'm sorry. I said it backwards.

A. That's okay.

Q. So Centocor was letting a competitor, Abbott, into the market?

A. Correct. For sales of Humira co-administered with Methotrexate. So the Humira to be used in a certain way, but absolutely.

Q. And the license provided for an effective royalty rate of 4 percent, did it not?

A. I think the license was 4 percent, but when you say effective rate, I think it was 2 percent. That was the effective rate.

Q. I think it started out at 4, and then it dropped to 2, correct?

A. Correct.

Q. So a royalty rate that was negotiated between Centocor, one of the parties to this hypothetical negotiation, and Abbott, the other party, the agreement -- the license that they entered into started out at 4-percent royalty and then dropped to 2 percent.

A. Right. And that was an agreement -- that was the license that Abbott paid Kennedy, and I discussed that, too.

Q. And if 2 percent is the appropriate royalty rate, that's seven times higher than this 15 percent that you've come up with, correct?

A. If your question is 15 seven times higher than 2, yes. If your question is that the appropriate royalty rate, the answer is no.

Q. My question is, is it seven times -- more than seven times higher than the royalty rate in that agreement?

A. 7-1/2, yes.

Q. All right. Now, let me switch subjects for a little bit.

You've heard -- you're familiar with the topic of license stacking, are you not?

A. Correct.

Q. And you're familiar with the fact that a royalty stack is basically the total amount of royalties a company must pay for certain parts of patented technology that they owe money to people for as royalties.

I think I may have said that clumsy. Let me start over.

A royalty stack is basically your total amount of royalties a company must pay to other companies for using their patented technology to make and sell a product.

A. Yes.

Q. All right. Now, I drive a Suburban, and just

so I can understand this, in all likelihood, General Motors, if that's its name today -- General Motors is selling a Suburban and it's sold, just to use my example --

A. Okay.

Q. -- General Motors might have to pay a percentage of a royalty to somebody who came up with antilock brakes, for example, right?

A. Okay.

Q. Somebody might have to pay -- or General Motors might have to pay a percentage to somebody for automatic windshield wipers, if they came up with that idea.

You see what I'm saying?

A. Yes, I do.

Q. And what you do is you figure out in my example how many different royalties General Motors would have to pay, and that total is what is called a stacked royalty.

A. Yes. I would say how much you have to pay, what the rate is.

Q. Right.

A. Yes, I agree.

Q. And it's not unusual for a healthcare company, for example, to use technology from multiple licensors,

is it?

A. Especially in biotech, yes.

Q. And you know that Centocor, for example, pays on a number of licenses for its sales of Remicade.

A. Yes, it does.

Q. You know that Centocor pays royalties to five different companies for technology that is included in Remicade.

A. Yes.

Q. And you're also aware, are you not, sir, that the highest royalty rate that Centocor has ever paid under one license for Remicade is 6 percent.

You know that, don't you?

A. I am not disagreeing with you, but I think it was 4-1/2.

The agreement says 6 percent. I think what they actually paid was 4-1/2, but I will agree with your 6.

Q. It started out at 6, and then it dropped to 4-1/2.

A. The agreement says 6. I think what the highest that they actually paid was 4-1/2.

Q. All right. So then, let me just ask you: The highest royalty rate Centocor has ever paid under one license for Remicade is 4-1/2 percent.

A. Yes. And I discussed that, yes.
Q. And Centocor is one of these parties to this hypothetical negotiation.
A. Yes, it is.
Q. Now, the total royalty stack that Centocor pays on Remicade, the total, is approximately between 11 and 14 percent, is it not?
A. Correct.
Q. And that is for five different parties.
A. Correct.
Q. In fact, Abbott pays royalties to multiple parties for the sale of Humira as well, doesn't it?
A. It does.
Q. And the highest rate Abbott has ever paid under one license for Humira is 6 percent.
A. Correct.
Q. So you've got both parties to this hypothetical negotiation, the highest rate they've ever paid for their respective products is either 6 percent or 4-1/2 percent, right?
A. That is correct.
Q. And you know that Abbott is currently paying royalty rates between .35 percent and 4.5 percent.
A. Correct.
Q. And you've seen testimony in documents

indicating that Abbott pays a royalty stack, again, all those royalties, of approximately 15 to 17 percent.

A. Right. I've seen documents that show the numbers smaller. I think there's confidentiality issues.

Q. Right.

A. I understand the 15 percent.

Q. It actually goes down to 7 then, doesn't it, percent?

A. I think so, yes.

Q. And that's for seven licenses, isn't it?

A. My recollection is five or six, but it's something in that order of magnitude.

Q. All right. Let's shift gears again. I want to talk a little bit about this licensing survey you told the Ladies and Gentlemen of the jury about.

A. Okay.

Q. Now, in your report, you reference a study that looked at royalty rates provided for in publicly available pharmaceutical agreements, didn't you?

A. I did.

Q. And that study -- and I may not pronounce it right, and forgive me if I'm mispronouncing it -- it's French. I think it's --

MR. BECK: Your Honor, I think it's Le

Nouvel, but I'm not going to guarantee that I've said that correctly.

THE COURT: Sounds like poor Arthur French to me.

MR. BECK: Close enough.

Q. (By Mr. Beck) Is that about right, Le Nouvel?

A. That's how I'm going to say it. That's fine by me.

Q. It's industry norms and reasonable royalty rate determination?

A. Yes.

Q. And what that study did, so that the jury might know, is that it analyzed 90 license agreements between 1984 and 2007, did it not?

A. Correct.

Q. And what that study showed was that the average royalty rate for the pharmaceutical industry, between 1984 and 2007, was 5.66 percent; isn't that correct?

A. That is correct. That's looking at both developed products and products that are not yet commercially available. Absolutely.

Q. In this hypothetical negotiation that we've been trying to walk through would be in 2006, which is within the time period of that study, correct?

A. Yes, it is.

Q. And so this study showed that the average royalty rate for the pharmaceutical industry for the time period that includes this hypothetical negotiation was 5.6 percent, correct?

A. Correct. But, again, that was for products that were commercially available as well as --

THE COURT: Doctor, he didn't ask you that. You've gotten to tell the jury twice now. Just start answering his questions and quit volunteering information, okay?

THE WITNESS: Yes, Your Honor.

THE COURT: You've testified a lot. I'm not talking to somebody's first time on the stand. So just answer his question.

If Mr. Sayles wants to clear up something, you know he will get an opportunity to.

Let's go.

Q. (By Mr. Beck) The royalty rate you have testified that is appropriate in this case is almost three times the royalty rate average in this state.

A. Yes.

Q. Now, let's talk about this LES study. You talked on direct examination about a survey conducted by the Licensing Executive Society, right?

A. Yes.

Q. And even the average royalty rate for launched products was below this 15-percent royalty rate that you're telling the jury about today, right?

A. Correct.

Q. And if you look at what the average was, high/low on your average amount, the average was -- was what; do you remember?

Let me help you. 11.6?

A. 11.6.

Q. 11.6 percent, correct?

A. Yes.

Q. And the median rate -- the median rate for launched products, meaning the most frequently occurring rate, was about half of the 15-percent royalty rate that you're advocating before this jury, correct?

A. Yes, with 7.5.

Q. All right. Let me switch to lost profits now.

Now, you're not offering any opinion as to when notice of infringement was given in this case, are you?

A. Correct.

Q. You're not?

A. I am not.

Q. And you know that the ladies and gentlemen of

the jury can decide whether or not damages, if any, should start on April 16th, 2007, for example, which would be the date that Centocor sues.

You understand that that could occur?

A. Yes, I do.

Q. And if the jury decides that there should be damages in this case and the damages should begin on April 16th, 2007, when they sued us, then that would significantly lower your damage number, wouldn't it?

A. It would decrease the number, yes.

Q. Decrease them significantly, wouldn't it?

A. Yes.

Q. Talking about millions and millions of dollars, aren't we?

A. Yes, you are.

Q. Now, with respect to the lost profits -- again, I've got to get it down to where I can understand it.

You followed what is called the market approach, did you not?

A. In general terms, yes. The Panduit Factors but market share, market approach, yes.

Q. Okay. And let me kind of say it -- let me give you an example to make sure I'm following what you're telling the jury.

When somebody's trying to sell their home, one of the ways to find out what the fair market value of your home is, is you look for comparable sales in the same neighborhood.

Fair?

A. Yes.

Q. You want to try to find out whether -- you've got a three-bedroom home with a two-car garage, and you want to sell it. You look at comparable sales to see if there are other three-bedroom homes with two-car garages in your general neighborhood.

You look at those sales, and that will give you an idea what the fair market value is. Be an indication?

A. If you're doing evaluation, yes.

Q. All right. And what you want to do is you want to find what are called comparables, don't you?

A. Yes.

Q. For example, you wouldn't compare -- say, if I'm selling a three-bedroom home with a two-car garage, you wouldn't be comparing that to a sale of a five-bedroom home with a four-car garage, right?

That would not be a fair comparison, would it?

A. Not right against -- I agree, yes.

Q. And you wouldn't be trying to compare a home

in Marshall or Gilmer or Longview or Port Arthur with something in Philadelphia or Los Angeles, would you?

A. Correct.

Q. That wouldn't be a fair comparable, would it?

A. Not unless you had some way to compare them, but yes.

Q. All right. Now, in this market approach, what you try to do is to find reliable data that will allow you to reallocate the market. That's what you're trying to do.

A. In general terms, yes.

Q. And so -- and this is what is called the but-for world, right?

A. Yes.

Q. And in this theoretical but-for world, what you do is you say to yourself, okay, I'm assuming that Humira is infringing the '775 patent. So in this but-for world, Humira comes off the table; it's no longer part of the market, right?

A. Yes.

Q. And so then you try to figure out, well, wait a minute. If Humira's off the market, what happens to those people, those patients that were using Humira? Where did they go?

A. Correct.

Q. And you're trying to reconstruct where those people go, right?

A. Yes.

Q. And you've got to make some assumptions there, don't you?

A. Yes, one does.

Q. In your opinion, for example, Humira, Remicade, and Enbrel are all substitutes for one another.

A. Yes, they are.

Q. And in your opinion, physicians and patients perceive all of them to be substitutes, correct?

A. Yes, in some indications. A little bit more than in others, but they do perceive them as substitutes, yes.

Q. All right. Now, you have been told in this matter to assume that a portion of the Humira sales are excluded for the damage calculation, correct?

A. Yes.

Q. And what you've done is you've removed all past sales from Humira in your damage calculation, haven't you?

A. I'm not sure I understand.

Q. Well, for example, your deposition was taken in this case, was it not?

A. Correct.

Q. And you knew that in your deposition that you were being asked to give your best evidence, the best evidence you had in response to the questions that were being asked, correct?

A. Oh, yes.

Q. And you did that, didn't you?

A. I tried, yes.

Q. And you were asked about, well, what about Humira? What do you do with Humira?

And you've testified that you've assumed that no Humira is available in the but-for world, correct?

A. Correct, no infringing Humira.

Q. And you were even asked about, well, wait a minute. What about Humira with Methotrexate? We've got a license for that.

You excluded that, too, because you believed that was infringement, didn't you?

A. I excluded it because I accounted for it. I didn't exclude it because it was infringing. I excluded it because of the arbitrator's ruling, and then I excluded infringing Humira.

Q. Did you exclude Humira with Methotrexate in your calculation?

A. Yes, I did.

Q. And you know we have a license for that. You know that.

A. Yes.

Q. And isn't it possible -- isn't it just possible that a man or a woman who was taking Humira in your but-for world with Humira off the table, that maybe they just might want to take Humira with Methotrexate, which we have a license to use?

A. And I said in my deposition I had already accounted for that in my analysis.

Q. Well, let me just ask you this: If you didn't do, if you didn't fully account for it, and the jury compensates for what you didn't do --

A. Okay.

Q. -- that would have the effect of lowering your damage number, wouldn't it?

A. It would.

Q. Now, let's talk a little bit about the difference in the products.

A. Okay.

Q. You know that Remicade is a chimeric antibody, right?

A. Yes.

Q. It means it's part mouse/part human.

A. That's my understanding, yes.

Q. You know that Humira is a fully human antibody.

A. Yes.

Q. No mice parts in Humira, right?

A. Correct.

Q. Let's talk a little bit about the administration.

The jury has heard this, and they've seen the way some of these things are administered here.

You know that Remicade is administered by an IV infusion.

A. I do.

Q. And you know it takes about two hours for the actual infusion, do you not?

A. Correct.

Q. And that's after you get into the doctor's office as opposed to sitting in the reception area, correct?

A. That's correct.

Q. It could take almost half a day or even longer, can't it?

A. It could take a while.

Q. And then Humira is subcutaneously administered, isn't it, sir?

A. Yes.

Q. And you've seen documents, have you not, where Centocor's own internal documents say, look, people prefer the subcutaneous injection, right?

A. Yes, I've seen those documents.

Q. And you've seen that the percentage -- the largest percentage of the market prefers that, right?

A. I've seen different percentages. You say a larger percent of the market. It's only in certain indications, but in those indications, yes.

Q. Let's talk about safety. The jury's heard a lot about safety, whether this product's safer than the other or not. And I'm not going to ask any questions about that, but I am going to ask you this:

What a patient believes or perceives with respect to safety is important, is it not?

A. I would assume so, yes.

Q. Just to use an example I can understand, if somebody says get on that ferris wheel and I say I don't believe it's safe.

Oh, no, it's safe. The fact that I've perceived it may not be safe may prevent me from getting on that thing, right?

A. It may, yes.

Q. And so regardless of whether or not it is or is not safe, people, in fact, are perceiving that

Remicade is not as safe as Humira and is not as safe as Enbrel.

Isn't that a fact?

A. In certain indications, yes, it is a fact.

Q. All right. There are a couple of documents that I want to show you and then, mercifully, I'm done, okay?

A. Okay.

MR. BECK: Let's bring up Plaintiffs' Exhibit 254, and if we can go to Page 36.

Q. (By Mr. Beck) And the jury has seen this, so I'm not going to spend a lot of time on it. You've seen this document which talks about how Remicade's mean performance rating on overall safety has declined significantly in this wave compared to the last, right?

A. I've seen that document and that page, yes.

Q. Internal Centocor document telling its management, hey, people, we're slipping in overall safety perception, right?

A. It says what it says, yes.

Q. All right.

MR. BECK: PX257, please, Page 33.

And, Your Honor, these are all in evidence.

THE COURT: Yes, I understand.

A. I'm sorry. Page 30?

Q. (By Mr. Beck) Page 33.

At the top of the page, it says Remicade ratings stayed steady on long-term safety, but are now significantly lower than both Enbrel and Humira.

Again, another internal Centocor document, right?

A. Correct.

Q. All right. Let me talk a little bit about market growth.

You agree that when a new product is introduced into the market, it can actually help grow the market.

A. It can, yes.

Q. And your Slide 9 showed the ladies and gentlemen an Abbott document, and one of the first things mentioned on that Abbott document was we want to expand the market.

A. Correct.

Q. They're talking about the whole market, right?

A. They were talking about the gastro market, yes, but the whole gastro market.

Q. And you told the jury, as I recall in direct, that both Remicade and Humira increased sales after Humira went on the market.

A. The entire market group and as part of it, both Humira and Remicade sales grew, correct.

Q. And you're familiar with the maxim that a rising tide lifts all boats.

A. I am.

Q. That's basically what we're talking about, isn't it?

A new product comes on the market, generates excitement. People start looking at biologics and everybody's -- and everybody's sales tend to grow.

Isn't that what we're talking about?

A. That's part of the story. That's not the full story.

Q. And in some instances, with more products on the market, you may have physicians that will prescribe the new product or one of the other products for a patient, right?

A. You could, yes.

Q. Even doctors who have never prescribed a biologic before, right?

A. Correct.

Q. And in determining lost profits, you have also assumed -- and there's a term in your report called bio-naive, and I want to make sure I know what bio-naive means.

A. Okay.

Q. In laymen's terms, to me that means nobody's ever used a biologic before; is that right?

A. Correct. That means that this is the first biologic a patient has used.

Q. Okay. So in determining lost profits, you've assumed that every person who's never used a biologic before, who had taken Humira in the real world, would take another biologic in the but-for world, even though Humira was not available?

A. Correct. If they were going to take a biologic, they would take another biologic, yes.

Q. And in your analysis, none of those patients would have chosen not to take a biologic at all if their biologic choice, Humira, was not available, right?

A. That is correct.

Q. In your analysis, none of those patients would have chosen to use a non-biologic at all, right?

A. They've already used the non-biologic. So in my but-for world, they would not go back to a non-biologic, yes.

Q. Fair point. Fair point.

On the sales, Remicade sales going up after Humira went on the market, you've got a table in your report, Table 9, don't you?

A. I do.

Q. And you've quantified the increase or the actual sales in the United States for Remicade in -- I believe it's 2006, 2007, and 2008. And I start at 2006, because you're using July 4, 2006, okay?

A. Yes.

Q. And in 2006, Remicade sales went up to 2.35 billion, didn't they?

A. In 2006, in the United States, yes.

Q. Yes.

Next year, 2.53 billion, right?

A. In the U.S., correct.

Q. Next year, 2.81 billion, correct?

A. Correct.

Q. And then you've got another table, Table 6, that tells us what the sales are internationally, don't you?

A. That's also in Table 9. It's the line below it, but yes.

Q. And sales going up internationally, too, right?

A. That is correct.

Q. Let's look at DX194.

So that the jury can see this, this is a June 2006 Centocor document; is that correct?

A. Yes, that is correct.

Q. If you would look at the page -- I believe it's Page 16.

MR. BECK: If we could emphasize the top there so the jury can focus on it.

Q. (By Mr. Beck) This internal Centocor document says: Biologic class penetration among RA patients increased in the first quarter of '06 and reached an all-time -- a new, all-time high, driven primarily by Humira.

Let me break that down. When you're saying or -- excuse me -- when Centocor says a biologic class penetration, are these brand new patients?

A. One second.

These are not necessarily brand new patients. If you look at the bottom given by the question, which is how many RA patients have you treated in the past six months.

So they could be brand new, or they could be patients that have failed another biologic.

Q. All right. Fair enough.

At any rate, biologic class penetration among RA -- that's rheumatoid arthritis patients?

A. Yes.

Q. Increased in the first quarter of 2006 and

reached an all-time high, driven primarily by Humira, right?

A. That's what it says, yes.

Q. Doesn't this tell you that by Humira going on the market, the rising tide lifts all boats? Isn't that what that's saying?

A. It definitely says that Humira helped increase the market, but I wouldn't agree with that last point.

Q. All right.

MR. BECK: DX519, bring that up, please.

Q. (By Mr. Beck) And by the way, the mode of administration of these biologics is a fact that it drives demand, correct?

Would you agree with that?

A. It's one of the factors, yes.

Q. And in reallocating the market share for lost profits, you didn't make any specific adjustment as a result of the mode of administration, did you?

A. I did not make a separate adjustment. It was part of the overall analysis I did.

Q. All right. DX519, the jury has looked at this very briefly, so I'm going to move very fast.

November 2005. Let's look at Page 12.

This is where Centocor internally is saying that there are three primary barriers to the use of

Remicade. Now, what that's telling you is these are three basic problems we've got with our product, Remicade, right?

A. It says what it says, yes.

Q. And it uses them in order of importance.

A. Yes. That's what it says.

Q. The first one on there is physicians believe that patients are overwhelmingly in favor of self-injection agents over infusion therapies and find them successful in the great majority of patients, correct?

A. That's what it says, yes.

Q. And then it goes on to say, on Page 37 --

MR. BECK: If we could switch to that, please.

Q. (By Mr. Beck) According to this Centocor internal document, it says: Believe that infusions are inconvenient for patients to schedule, that their patients have a strong preference for injection therapy.

Do you see that?

A. Page 27?

Q. 37.

A. Sorry. That's what it says, yes.

Q. Page 39, if you'd look quickly at that, please, Doctor.

A. Okay.

Q. It says -- this is entitled: Patients appear to be satisfied with injectables.

A. Yes.

Q. Right?

And Humira and Enbrel are injectables, are they not?

A. Yes.

Q. And if you will look, it actually quotes a patient. It just says, look, I work every day from 11:00 to 7:00. I don't have time to sit in a chair for four hours.

That's a factor that patients are considering in whether to choose Remicade or not, right?

A. That is a factor, certainly, for that individual. Absolutely.

Q. Or to choose an injectable, correct?

A. Correct.

Q. Look at Page 41. These are conclusions. Remicade is niched for moderate to severe PsA patients who have failed at least one other biologic. The vast majority of patients do not request a specific biologic for treatment of PsA.

What that's basically saying is that Remicade has a niche for PsA patients, correct?

A. In the PsA market, yes.

Q. Let's look at DX189. This is dated January 18th, 2007, internal Centocor document, entitled Remicade strategy.

You've seen that document before, have you not?

A. I have.

MR. BECK: Let's look at Page 35.

Q. (By Mr. Beck) In the last box, it says patients express strong preference for a particular product based on particular attribute; for example, subcutaneous injections as the preferred route of administration.

That's what this document says in the discussion of Remicade strategy, correct?

A. It says that, yes.

Q. And you know that these documents are put together so management can look at them, examine it, and rely upon, and make business decisions.

A. That's my understanding.

Q. Let's lastly look at 877.

The jury has seen this earlier; you've seen it before, have you not?

A. I have.

Q. This is a transcript of a telephone call that

involved the Worldwide Chairman of Pharmaceutical Group for Johnson & Johnson.

You've seen that?

A. Yes.

MR. BECK: All right. If we may look at Page 4, please.

Q. (By Mr. Beck) And you know that what Ms. McCoy was doing was talking to people who were on this telephone conference. You know there were analysts on this conference, too.

A. Yes.

Q. And you could tell by looking at the document that there were going to be people on that conference call that were going to be relying upon what she said.

A. I would assume so.

Q. And that what she was saying was going to be relied upon by people in the marketplace who were investing, right?

A. That would be my assumption, correct.

Q. And you know that it's important for a lot of reasons, one of which because it's the right thing to do, you should be accurate, right?

A. Correct.

Q. And if you look at Page 4, Ms. McCoy is telling the investing public about Simponi, their new

fully human antibody product.

Do you see that?

A. I do.

Q. And what she says is: Simponi, as I mentioned, was just recently approved.

And you know it's just been on the market a couple of months.

A. Yes.

Q. It's a human anti-TNF, best-in-class dosing, mostly subcutaneous.

A. Monthly subcutaneous, yes.

Q. Monthly. I'm sorry. I misspoke.

So basically, what they're doing is they're trying to catch up with the Joneses here, aren't they?

They're trying to come up with a fully human antibody and one that you can inject subcutaneously.

That's what they're doing, isn't it?

A. I think it says what it says. If you want to know what I think it says, I'll tell you, but it says what it says.

Q. And if we'll look at -- she goes on to say -- if I can find it on here -- yes.

And we believe -- she says: And we believe this will be very welcome by patients relative to the subcu -- that's the subcutaneous component, right?

A. Correct.

Q. And also allow us to compete in the subcu area. Today, obviously we have Remicade. 40 percent of the market today is in IV, where we are with Remicade. The other 60 percent -- talking about the market, right?

A. Yes.

Q. -- is in subcu, and this enables us to get into the subcu market with a very competitive product.

A. Yes. This would be Centocor's first subcu product, yes.

Q. All right. Look at Page 5.

Ms. McCoy then talked about Remicade and Simponi and how those two Centocor products compliment one another.

Do you see that?

A. I do.

Q. And she says: You mean between Remicade and Simponi?

So we see them as complementary products. Obviously, Remicade is an IV-based product; Simponi is a subcu execution, correct?

A. That's what it says, yes.

Q. And then she goes on to say -- if we go down here -- where we see the opportunity for Simponi is to go into the subcu market where we don't compete today.

That's what she's telling the investing public, right?

A. Correct. Because Simponi is the first subcu product. Absolutely.

Q. And she says: We see there's an advantage relative to the dosing in terms of once monthly as well as we've had a lot of favorable commentary relative to our autoinjector because it's less painful, and it's easier for people with RA to use, correct?

A. Yes.

Q. So you have the global head of pharmaceuticals from J&J saying that Remicade does not compete in the subcutaneous market, correct?

A. That's what this statement says.

Q. Humira is in the subcutaneous market, isn't it?

A. Yes, it is.

MR. BECK: Pass the witness, Your Honor.

MR. SAYLES: May I have that document?

REDIRECT EXAMINATION

BY MR. SAYLES:

Q. Dr. Gering, you were just now asked some questions regarding Sheri McCoy's statements.

Do you see that?

A. I do.

Q. Is it your understanding that this is a telephone conversation that she was on?

A. Yes, that's my understanding.

Q. A transcript prepared by Bloomberg, some agency?

A. Yes.

Q. Have you read the whole thing?

A. I have not read the whole thing. I have read sections of it.

Q. Have you read the portion about what Sheri McCoy said?

A. I've read some of the sections, yes.

Q. All right.

MR. SAYLES: Now, let me have this paragraph that we were just talking about.

All right, right there.

Q. (By Mr. Sayles) Let me take you to the end of the sentence.

MR. SAYLES: And would you highlight starting with so we see?

Q. (By Mr. Sayles) If you would, let's -- let's read that into the record, that last sentence that I've highlighted.

A. So we see them as very, very different. Simponi will be targeting people who have either failed

on certain -- NIT anastin will be up there after that as well as going more directly with the competitive set in that space.

Q. In your analysis, did you recognize that there was a competitive set where there were folks who preferred an injectable over an IV?

A. Absolutely. And there are data that quantify that, and I used that data.

Q. Have you taken that completely into account in your numbers?

A. Yes.

Q. And is there anything about Sheri McCoy's statement here that's been shown to you now by Mr. Beck and that you've read a portion of that changes your opinion in this case?

A. No.

Q. Do you feel like in any way is your opinion inconsistent with this?

A. No, not at all.

Q. You were asked some questions by Mr. Beck about convenience, and he asked you a whole line of questions about that.

Do you recall that?

A. Yes.

Q. Have you considered convenience in your entire

analysis?

A. Absolutely. Convenience really has two pieces to it. There is the subcutaneous versus the IV. Clearly, self-injection is more convenient than going to a doctor's office and sitting there for a number of hours.

But then there's also the frequency of administration. That's also convenience. Every two weeks versus every eight weeks. So there's two components to it, and I have considered both of them.

Q. Have you ignored the convenience in any way?

A. No.

Q. And you were asked some questions about safety.

Do you recall that?

A. I do.

Q. And with regard to safety, have you taken that into account?

A. Yes, I have.

Q. And was that reflected in the numbers that you provided to the jury earlier in your opinions?

A. Absolutely. That's reflected into the underlying data that I used to do the adjusted market share analysis to quantify what share of the market Remicade would have achieved in this but-for world where

there's no infringing Humira.

Q. You were asked some questions about Exhibit 254 relating to safety.

Do you remember that?

A. Yes.

Q. Do you have it up there?

A. Now I do.

MR. SAYLES: All right. Can we get 254, please?

And would you go to Page 21, please?

Q. (By Mr. Sayles) Is this page significant in terms of your analysis and consideration of the effectiveness of Remicade?

A. Yes. I used that page in con -- that deals with Remicade. Two pages back is a similar page that deals with Humira. That's so the underlying data -- that would be Page 23.

Q. All right.

A. And if you can -- you look at the safety -- the plus and minuses on the safety, they look very similar in the raw data.

So that's Humira. So if you go one, two, three, four bars down, you see safety as a big red negative and a small blue positive. That means a number of people choose -- have an issue with safety for not

prescribing Humira, and a number of people have a blue, a positive, for prescribing Humira.

And that data looks very similar to Page 21, which is the same -- same set of bar charts but looking at Remicade.

So, again, if you go down one, two, three, four, you can see the safety fairly substantial red negative and a fairly small blue positive.

But, again, Humira and Remicade look very similar amongst physician preferences in this same study. That's the raw data.

Q. If this jury were to make a reduction in the damages that you have given your opinions about on the basis of convenience, would they be making a deduction on something you've already considered?

A. In my opinion, yes.

Q. And taken fully into account?

A. That was my intention. I believe I did that.

Q. And same thing with regard to safety, would they be making a deduction, if they did that, on the basis of something that you had fully considered and taken into account in the calculations?

A. In my opinion, yes.

Q. You were asked a question about Defense Exhibit 555, and we don't need to pull it up, but that

was referred to by Mr. Beck as a settlement agreement between CAT and Abbott.

In your experience, what consideration do you give to settlement agreements?

A. Typically less consideration. That's why I mentioned that it was a settlement of an underlying document that had a 6-percent royalty rate.

Q. And did you take that into account?

A. I -- I looked at both the original agreement, as well as the settlement agreement. And all of those license agreements that I went through with Mr. Beck were in my analysis, and I took them all into account.

Q. Again, in the interest of time, I want to refer you to Defendants' Exhibit 220 in your book but not on the screen.

And do you recall that Mr. Beck asked you some questions in which he said in the question that -- that there was a royalty involved where Abbott agreed to pay 2 percent?

A. Correct.

Q. Actually, if you look at Exhibit -- Defense Exhibit 220, that's the license that Centocor got from Abbott, isn't it?

A. I believe -- I believe it is. That's the -- that's the -- there were agreements -- there were two

agreements; one where Centocor led Abbott onto the market; and this one is the one back where Centocor got certain rights that were gained to potentially use with CNTO148 with Simponi.

Q. Actually, it was the reverse of what Mr. Beck said. It would be Centocor that would be paying Abbott 2 percent instead of Abbott paying Centocor 2 percent; is that right?

A. Correct. I think both agreements have a 2-percent number in them.

Q. All right. Is this the license agreement about which we saw, the e-mail, where Abbott internally valued the rights that were being conveyed to Centocor of $1.6 billion?

A. Correct. That's the same -- the same document being spoken about.

Q. You were asked some questions about many items that you have assumed in this case.

Do you recall that line of questioning?

A. I do.

Q. Is there anything that you have assumed in this case that is out of the ordinary for a proper analysis of damages in a patent case?

A. No, there is not.

Q. In fact, in this case, have you reviewed the

report of the Defense damages expert?

A. I have.

Q. Did he make the same or similar assumptions that you did as far as a framework is concerned?

A. Yes, he did.

Q. You were asked a few questions about the co-administration of Methotrexate and the fact that that is licensed. And I think we touched on that on your direct.

Do you recall that subject?

A. I do.

Q. Is there anything that Mr. Beck asked you that causes you to change your opinion about accounting for that?

A. No, there is not.

Q. Straight out, did you account for that?

A. Absolutely. I think I mentioned it a few times. I quantified these sales of Humira that were administered or co-administered with Methotrexate, and I extracted them from the calculation at the beginning so that they didn't show up at either the lost profits or the reasonable royalty numbers.

Q. And when you were being asked questions about various royalty agreements by Mr. Beck, do you recall that subject?

A. I do.

Q. And he went through several that had varying rates, some of them lower than you're suggesting here.

A. Yes.

Q. And all of them, except the Abbott-Cordis, were below the amount you're suggesting here.

A. Correct. And because many of them were for technologies, for products that were not yet commercialized as we went through with Mr. Beck.

Q. When you're buying a house and there are comparables that are being considered, are you familiar with the concept that there are usually adjustments made to those, taking into account the circumstances of whatever is considered a comparable?

A. It may be because sometimes comparables aren't a hundred-percent comparable. They're somewhat comparable, so you make an adjustment.

Q. Did you consider these rates that Mr. Beck brought to your attention?

A. Absolutely.

Q. Do you stand by your opinion as to a reasonable royalty?

A. I do.

Q. You were asked a few questions about the fact that stent technology is different than what we're

dealing with in this particular case; is that right?

A. Yes.

Q. Now, let me ask you, hypothetically, if a party has a patent that's never been licensed and someone infringes that patent, just because there aren't any licenses out there at all, does that mean they can't get a reasonable royalty?

A. No.

Q. And in this case, you have considered the license agreements that were exchanged between the parties.

A. Yes, I have.

Q. But you could do this same analysis and would have to do this same analysis if this were a case where there weren't any agreements on a reasonable royalty.

A. Correct. One looks for all the agreement -- if there are no agreements that are produced to analyze, then you have to go forward with the analysis without doing that.

Q. On this topic of stents being in a different field than we're talking about in this case, did you read the depositions of the persons that were involved in the negotiations that actually took place beginning in December of '05 but didn't result in any sort of agreement?

A. With respect to the stent agreement or other agreement?

Q. With respect to the negotiations.

A. I read depositions and saw information about negotiations that went nowhere.

Q. Did you see in your review and analysis that Abbott put on the table in the negotiation something called DES?

A. I believe I did, yes.

Q. And what is DES?

A. I think that that refers to -- the S is stent, so it refers to the stent technology at that point in time. There was discussions about negotiating or sharing certain baskets of intellectual property in order to -- to reach an agreement.

And Abbott put the stent technology into that negotiation, but no agreement was reached. So Abbott put that forward when they were discussing licensing with Centocor.

Q. You were asked some questions about the growth of the market.

A. I was.

Q. And in your analysis in this case, did you take into account the growth in the market?

A. Absolutely. And in many cases, the growth in

the market came from what's called failures. So, for example, in gastro, a tremendous amount of growth of the market came -- because Remicade was their first, many patients tried Remicade. Some patients tried Remicade and it didn't work. So they were Remicade failures.

Once Humira came onto the market, then those patients now had another biologic to try. So that grew the market at that time period. So some of the growth did not come at the expense, for example, of Remicade in that instance. Some of it may have.

So I accounted for it, and I understood it.

Q. You were asked a few questions about the Le Nouvel study.

Do you recall that?

A. I do.

Q. And Mr. Beck specifically asked you some questions concerning royalty rate averages out of that study.

A. Yes, he did.

Q. In your opinion, is that the appropriate item to look at in that study?

A. Well, I definitely looked at that study. So in one sense, it was appropriate. It wasn't the most appropriate because that 5.66 average included all agreements. It included agreements where there was a

commercially available product, and it included agreements that there wasn't.

The study that I highlighted today was one which differentiated between a launched product and non-launched product. But I looked at them both.

Q. Dr. Gering, finally, in the examination by Mr. Beck, did you see or did he ask you to consider anything that you had not previously seen or considered in your analysis?

A. No, he did not.

Q. And do you stand by your opinions in this case?

A. I do.

Q. And in terms of available data to evaluate, how would you characterize this case in terms of information available?

A. There was a lot of information. It was much more information than typical. These are very big companies, very big drugs, and they did a lot of studies. So there was a lot of information to look at.

MR. SAYLES: I'll pass the witness.

REDIRECT EXAMINATION

BY MR. BECK:

Q. You were in the courtroom when Mr. Dow testified --

A. I was.

Q. -- this morning.

And you heard Mr. Dow talk about these negotiations between Centocor on the one hand and Abbott on the other hand in December of 2005 and early 2006.

A. Correct. Yes, I did.

Q. Discussed those three conversations the parties had back and forth.

A. There were three conversations. There were negotiations that went from '06 to -- well, '05 through '07, which were slightly different, yes.

Q. And those discussions involved someone from Centocor saying, hey, we think that you're infringing our patent, or some words to that effect.

A. Those three discussions, yes.

Q. In those discussions, you never heard either party say anything about a 15-percent royalty rate, did you?

A. Correct.

Q. Thank you.

MR. BECK: That's all.

MR. SAYLES: I have nothing further of this witness, Your Honor.

THE COURT: All right. You may step down.

Ladies and Gentlemen, we'll take an afternoon break. I have to take a couple of things up with counsel, so we'll come back in at 3:35. 3:35.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: Yes, y'all can sit down. The Court's in recess.

I need to see counsel at the bench.

(Bench conference.)

THE COURT: Are you about to rest?

MR. SAYLES: Yes, sir. The stipulations will take me about three minutes.

THE COURT: Okay. After you rest, can we stipulate that we'll go ahead and proceed with the agreement that you can later present your motions or JMOLs, and they will be deemed as presented at the close -- and the time you rest?

MR. SAYLES: We would agree that they're timely.

THE COURT: That way I don't want to bring the jury -- that's agreeable?

MR. BECK: That's agreeable.

MR. SAYLES: It is agreeable.

MR. LEE: Can we do it orally or do you want us to --

THE COURT: No, orally is fine. Do it however you want to do it. I'm just saying if you want to reduce it to writing, we'll take them up either late this afternoon or in the morning.

MR. LEE: Orally.

THE COURT: Okay. That's fine. However you want to do it. I'll see you back -- I just want us to keep going, and then maybe we'll let the jury go this afternoon, and we can take them up then.

Is that alright?

MR. LEE: That's fine.

THE COURT: Are you ready to go with your witnesses?

MR. BECK: We're ready.

THE COURT: Okay. Now then, do we need to get into this issue about your expert, exactly what he's going to be able to say about --

MR. LEE: We said that it probably won't be until tomorrow, and I will approach the side-bar before I ask the questions, and I'll tell you what questions we're going to ask.

THE COURT: Well, here's what I think I'm inclined to tell you so that you know: Your expert, as I understand it, said something to the effect, if the '92 application --

MR. LEE: Correct.

THE COURT: -- then it would -- if --

MR. LEE: Yes.

THE COURT: Then, you know, it would be anticipated. The if doesn't exist. You know, I've ruled that if out, so -- I mean, he can express an opinion that's anticipated to '94, but he's not going into the '92.

MR. LEE: Okay. And that would go for both -- both parties then, Dr. Adams and Dr. --

THE COURT: They're going -- whatever they said -- I've read that portion of your expert.

MR. LEE: Right.

THE COURT: And both experts -- it looks like to me, if we just -- everybody stays with what their expert says, has said in their report, then we don't have to get into these issues.

Do you agree with that?

MS. ELDERKIN: We have no intention of having Dr. Adams testify outside his report, but I want to make sure because Mr. Lee just said something that I don't think is consistent with what I'm thinking.

THE COURT: Y'all neither one need to know what each other are thinking. You just think you do. Nor do I.

MR. BECK: I'm not thinking anything.

THE COURT: I threw you that line on Port Arthur. It just ticks me off.

MR. LEE: Here's what I would ask him. If it's not -- if we can't, we can't -- we would just ask him, Doctor -- I would show him Paragraph 158 of Dr. Adams' report where he says there's a '92 application. It is enabled and just say --

THE COURT: I have ruled on it. No. We're not going to get into that. That if doesn't exist. I'm not going to allow her to say that the '92 was enabled. So that's contrary to what I have ruled.

MR. LEE: Okay.

THE COURT: That's why I'm saying that if is out of the case.

MR. LEE: All right. If the '92 application is out, then I'm probably not going to go into it at all.

THE COURT: I'm just saying I'm not going to allow her to introduce testimony that the '92 application was enabled. I've ruled on that.

MR. LEE: Okay.

THE COURT: I'm not going to allow any expert testimony to say something that I've ruled as a matter of law to the contrary.

MR. LEE: But let me do this, if I can think about it, but I won't ask any questions.

THE COURT: We're going to think about it. That's why I want to have this conversation up here. I would rather have it now than right in the middle of a battle where I might -- you're going to throw something at me and I'm going to say he's thrown that curve at me again.

MR. LEE: He'll hit me in the head.

THE COURT: No, he wouldn't -- he won't even recognize that curve ball. I want to ask him -- I wanted to ask him something about human antibodies here in a little bit.

MR. BECK: I know about those human antibodies.

(Bench conference concluded.)

(Recess.)

COURT SECURITY OFFICER: All rise.

(Jury in.)

THE COURT: Please be seated.

All right. What have you got there, Mr. Sayles?

MR. SAYLES: May it please the Court.

At this time, we are going to offer a few additional stipulations. I'd like to do that now.

THE COURT: All right.

MR. SAYLES: With respect to Stipulation 12, the parties have agreed on an addition to it, so I'd like to read it as the parties have now agreed.

This is Stipulation 12: Abbott's U.S. Humira sales, by indication and through April 2009, are reflected in Defense Exhibits 468, 469, and 985.

Next, I'm going to read into the record and for the benefit of the jury, Stipulation No. 7.

CNTO Ortho Biotech and New York University are co-assignees of the '775 patent.

Stipulation No. 11: All of the D2E7, the antibody contained in Humira, is manufactured by either ABC or ABL in the United States.

Stipulation No. 20: Remicade was first approved by the Food & Drug Administration on August 24th, 1998.

21: Humira was first approved by the Food & Drug Administration on December 31st, 2002. That concludes the reading of the stipulations.

THE COURT: All right. Who will be your next witness?

MR. SAYLES: Your Honor, at this time, may I confer with my co-counsel for just a moment?

THE COURT: Yes.

(Pause in proceedings.)

MR. SAYLES: At this time, the Plaintiffs rest their case-in-chief.

THE COURT: All right. Thank you.

Defendant ready to proceed?

MR. BECK: We are ready, Your Honor.

THE COURT: All right. Who will be your first witness?

MR. BECK: We'd like to call Dr. Jochen Salfeld, please.

THE COURT: Okay.

MR. BECK: Dr. Salfeld, would you raise your right hand?

(Witness sworn.)

MR. BECK: May I proceed, Your Honor?

THE COURT: Please do.

JOCHEN SALFELD, Ph.D., DEFENDANTS' WITNESS, SWORN

DIRECT EXAMINATION

BY MR. BECK:

Q. Please introduce yourself to the jury.

A. My name is Jochen Salfeld.

Q. And by whom are you employed, Dr. Salfeld?

A. By Abbott Laboratories.

Q. And what is your current position with Abbott Laboratories?

A. My position is Divisional Vice President, Biologics.

Q. And in your capacity as Division Vice President for Biologics, how many people work under your direction and supervision?

A. I'm a director of around 60.

Q. And are all of those 60 people scientists?

A. Except for my assistant, yes, they are.

Q. And tell the jury what your duties and responsibilities are as Division Vice President for Biologic Discovery.

A. My duties are to oversee the discovery of novel therapies for different diseases.

Q. And without going into specifics, because there's a competitor in the courtroom, what new medicines or drugs are you working on?

A. We are working on new biologic therapies to treat cancer, Alzheimer's, viral diseases, and immune diseases.

Q. And without, again, revealing any trade secrets, if you will, is that research looking promising?

A. I'm very excited about it, yes.

Q. Now, before we get into the details of the case, I want to give the jury a little idea of your

background so they get to know you a little bit better.

Are you a married man?

A. Very much so.

Q. And I'm afraid to ask you -- follow up with that question, but let me ask you this: How old a man are you?

A. Fifty this year.

Q. And how did you and your wife meet?

A. In the lab.

Q. You and your wife met in the laboratory?

A. Yes, we did.

Q. Was it love at first sight?

A. Not from her side.

Q. Okay. Now, the jury's going to hear in a minute, you have a Ph.D., correct?

A. I do, yes.

Q. Does your wife also have a Ph.D.?

A. She does, yeah.

Q. And do y'all have any children?

A. Three of them: A daughter, 17; our son is 15; and our other son is 10.

Q. And where do y'all live?

A. Massachusetts.

Q. And where in Massachusetts?

A. In a small town called North Grafton, around

Boston.

Q. All right. Now, I can tell you don't have a Texas accent, so will you tell the ladies and gentlemen of the jury where you were born?

A. I was born in what used to be western Germany.

Q. And when did you come to the United States from Germany?

A. In May 1987.

Q. That was about 20 years ago.

A. Yes.

Q. And tell us a little bit about your educational background. I know that your -- the system in Germany is a little bit different than here, but tell us what the equivalents are in Germany that are similar to what we do here.

A. I received what corresponds to a Master's degree at -- in Heidelberg, University of Heidelberg, and then I took a Ph.D. from Heidelberg as well.

Q. And so you have the equivalent of our Master's degree and the equivalent of a Ph.D. degree?

A. That is correct.

Q. So that the jury might know, when you received your Ph.D. degree, did you get that degree with high honors?

A. Yes, I did.

Q. And have you been a scientist your whole professional life?

A. Yes, I have.

Q. Now, at least in this country, when you work on a Ph.D., you have to write a paper, a thesis. Did you have to do that?

A. Yes, I did.

Q. And what was your thesis on?

A. On hepatitis B virus.

Q. Now, tell the jury whether or not you always wanted to be a scientist. You know, some people know from the day they're born what they want to do.

Did you always want to be a scientist?

A. I did not.

Q. And tell the ladies and gentlemen of the jury what you were torn between.

A. I was torn between becoming a scientist and becoming a farmer.

Q. That's a pretty -- pretty wide choice there.

And tell the jury how it was that you were even interested in farming.

A. I grew up on a very big research farm where my dad -- I was doing research on how to actually farm even better. It was a huge farm.

And I also spent all my summers on my uncle's

dairy farm, and I always wanted to be a farmer as a young boy.

Q. All right. Now, when you said you grew up on a research farm, you actually lived on a farm, and your father did research there.

A. Yes, I did.

Q. Is he a scientist, also?

A. He was.

Q. And then for how many summers as a young -- starting as a young boy, did you work at your uncle's dairy farm?

A. About 15 -- about 15 years.

Q. All right. Did you enjoy working at that dairy farm?

A. Very much so.

Q. And what did you have to do there?

A. Everything, plow fields, hay -- baling hay, milking cows, everything.

Q. All right. And whenever you decided to apply to the university in Germany, did you have to put down two choices, not just one?

A. Yes, I did.

Q. And what were the two choices you listed when you applied to go to school?

A. First choice was biology, and the second

choice was agriculture.

Q. And you eventually ended up being a scientist?

A. Scientist.

Q. So farming lost out.

A. Lost out, yeah.

Q. After you got your Ph.D., Dr. Salfeld, did you do any postdoctoral work?

A. Yes, I did. I did a postdoctoral fellowship at the Center for Molecular Biology in Heidelberg.

Q. All right. And what type of postdoctoral work did you do?

A. Looking at -- further at the gene expression and hepatitis B virus, which is a very severe agent that affects the human liver.

Q. All right. Now, we've got you with your Ph.D. degree. We've got you doing your postdoctoral work.

After you completed your postdoctoral work, what did you do?

A. I actually did a second postdoctoral work in the U.S. at the Dana Farber Cancer Institute, Harvard Medical School in Boston.

Q. All right. And after you completed all of your postdoctoral work, what did you do?

A. I then joined what was then BASF.

Q. All right. And when did you join BASF?

A. In January 1990.

Q. And did that company, BASF, eventually become part of Abbott?

A. The pharma portion of BASF became part of Abbott, yes.

Q. All right. You used a word there. The -- what portion?

A. The pharma, the pharmaceutical portion of BASF became part of Abbott.

Q. And when was that?

A. In the year 2001.

Q. So would it be fair to say you have been with the same company your whole life?

A. I have, yes.

Q. First with BASF, and then it became part of Abbott, and you just continued on?

A. I did, yes.

Q. Are you the named inventor on any patents?

A. Yes, I am.

Q. Approximately how many?

A. I think between 15 and 20.

Q. All right. Now, just very generally tell the ladies and gentlemen of the jury what subjects your patents deal with.

A. They deal with therapeutic antibodies,

primarily, but they also deal with gene expression.

Q. Therapeutic antibodies. Layman's terms, tell us what that is.

A. It's an approach of using natural binding proteins to reach a therapeutic effect.

Q. To try to do what?

A. To treat diseases, treat various severe human diseases.

Q. You used the term gene regulation (sic). Do we all have genes in our body?

A. We do.

Q. Approximately how many do all of us have?

A. Between 25,000 and 30,000.

Q. And why do you scientists study our genes?

A. We have to study the genes because we have to understand why people get sick.

The first step in drug discovery is, why is somebody even developing a disease? Because we have to do -- find the difference between normal and who is normal and somebody with a disease and then say, can I define why somebody actually has a disease? And that information goes into our drug discovery program.

Q. All right. Would it be fair to say that you research genes to try to figure out what causes disease?

A. Exactly.

Q. And then by further study, you can determine how to somehow cure or help those diseases.

A. Exactly.

Q. Now, let's talk a little bit about Abbott itself.

When was Abbott founded?

A. In 1888.

Q. And by whom was it founded?

A. By Dr. Wallace Abbott.

Q. And who was Dr. Wallace Abbott?

A. He was a practicing physician who also owned a pharmacy.

Q. And where did he practice and own that pharmacy?

A. Illinois.

Q. And where in Illinois?

A. In Chicago.

Q. Now, what -- well, let me just ask you, what's the business of Abbott?

A. Abbott is a global diversified healthcare company with a number of different businesses.

Q. And tell the jury just very generally what those type businesses are.

A. They are the pharmaceutical business. They have a very large diagnostic business. They have a

large medical device business. And then they have a nutrition business.

Q. All right. Let's talk very briefly about each of those.

The pharmaceuticals. You develop pharmaceuticals, right?

A. Yes.

Q. These are drugs and medicines.

A. Yeah.

Q. And the devices, the medical devices, give us an example of medical devices.

A. Medical devices include stents that you've already heard about, little mesh tubes that are very important to keep arteries open after intervention.

Q. All right. And you used the term diagnostics. Are these machines to help test patients when they go to a doctor's office?

A. Yes. We have a number of devices. We have very large machines that test -- when you go into the doctor and you have your blood work done, they can run all the tests there.

We also have specialty tests, like the freestyle device that helps you identify glucose levels in diabetes patients.

Q. All right. And what about nutrition? Give

the jury some examples of what you do in the nutrition area.

A. Abbott's selling a lot of nutritional supplements for children, Pediasure, Pedialyte, Ensure, Similac. They also have specialty nutrition, like Glucerna for diabetes patients.

So a whole set of children, adult, and specialty nutritions.

Q. All right. Now, with respect to the pharmaceuticals, because that's what we're really talking about in this case, tell the jury the type of serious medical conditions that the pharmaceuticals that Abbott works on address.

A. We have medicines for sever infections. We have medicines for thyroid disease. We have medicines for autoimmune disease. We have medicines for cancer and others.

Q. And the type of autoimmune diseases we're talking about are what?

A. Rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and others.

Q. Crohn's disease?

A. Crohn's disease.

Q. Now, these diseases -- and you personally work in this area, do you not?

A. I am, yes.

Q. And are any of these diseases very personal to you?

A. Yeah.

Q. Why is that?

A. My maternal grandparents, my mom -- my grandmother died of arthritis. Arthritis is a very severe disease, and many people die of it. Some people die of the disease. My grandmother was one of them. My grandfather died of cancer. So my mom was an orphan.

So I've always wanted to do something about treating these diseases. And then my dad died of Alzheimer's, so I want to do something for Alzheimer's.

So I'm working on all three areas now.

Q. All right. And where is Abbott headquartered?

A. Illinois.

Q. And how many employees in the United States does Abbott have?

A. About 30,000.

Q. Now, I want to shift and talk a little bit about Humira.

What is your connection with Humira?

A. I co-led the discovery of Humira, and then I was responsible for the early phase of the Humira development, and I stayed on the Humira team all the way

until launch.

Q. Okay. You said you co-led --

A. I co-led.

Q. -- the Humira team?

A. The team that discovered Humira, yes.

Q. And what is Humira?

A. Humira is a fully human antibody that binds TNF-alpha with high affinity, so it's very sticky for TNF, and it turns off the function of TNF.

Q. And what is D2E7?

A. D2E7 is the lab name that we gave Humira when we were doing the lab research.

Q. And you scientists can just make up any name you want and give it to a product, right?

A. Scientists can be very crazy and give strange names to things, yes.

Q. In fact, what -- tell the jury what the name of D2E7 was before it became D2E7.

A. It was the actually Eric, the name of a soccer star.

Q. All right. And then it became -- went from Eric to D2E7 to eventually Humira?

A. Correct. Correct.

Q. And the jury's heard this, so I just want to touch it very briefly.

What type of diseases is Humira used to treat?

A. It is used to treat rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease.

Q. Now, when -- eventually, Humira -- well, let me ask this: At some point, Abbott had to make an application to the Food & Drug Administration.

A. They did, yes.

Q. And you did that.

A. We did.

Q. And when did Abbott make its submission to the Food & Drug Administration in this country?

A. In early 2002.

Q. And how long did it take to get FDA approval?

A. It was approved at the end of the same year, New Year's Day 2002.

Q. And when was -- so that -- so when was Humira actually approved by the FDA then?

A. New Year's Eve -- I apologize. New Year's Eve 2002.

Q. Now, you seem to be pretty sure of that. Is that right?

A. I'm very sure.

Q. And why are you so sure?

A. Because while getting ready for my New Year's

Eve party in 2002, I got a phone call from our head of the company to congratulate myself and the team for the success.

Q. Is that a date you'll always remember?

A. It is, yes.

Q. When was Humira first put on the market in the United States as a treatment option?

A. Shortly thereafter, 2003.

Q. And when was Humira first put on the market -- well, at the time Humira was approved by the FDA and put on the market, were there any other fully human anti-TNF antibody products on the market?

A. There were not.

Q. Are there any other fully human anti-TNF products on the market today?

A. Yes, there are.

Q. And what is the name of that product?

A. Simponi.

Q. And whose product is it?

A. Centocor's.

Q. And when did Centocor launch its fully human anti-TNF antibody product?

A. About two months ago.

Q. Between early 2003, when Humira went on the market in the United States, and April of 2009, when

Centocor launched its Simponi product, was Humira the only fully human anti-TNF product on the market?

A. Yes, it was.

Q. Now, I want to shift gears a moment and talk a little bit about the administration of Humira. The jury's heard some testimony about this, so I'm not going to spend a lot of time on it.

Could you --

MR. BECK: Your Honor, may he stand up just to show the jury how the injection --

THE COURT: Yes.

Q. (By Mr. Beck) Doctor, if you would just stand up and just show the jury how Humira is administered.

A. All you have to do is take a little pinch here (demonstrating), and then you can inject directly. It's a very convenient delivery device.

Q. Thank you. You may sit down.

A. (Complies.)

Q. And who administers the injection of Humira?

A. In about 75 percent of the cases, the patient themselves; about 14 percent, a family member or friend; and 8 percent, a healthcare provider. That's a study as of 2008.

Q. Now, the jury has seen some surveys and market research that Centocor has done. Do y'all do that same

thing?

A. Yes, we do.

Q. And did the company do surveys or focus groups to find out what patients preferred by way of administration?

A. Yeah. I do remember -- yes. I do remember that early in development, we actually had focus groups of patients to actually see what kind of device they would prefer, because you have already heard that patients with arthritis have very limited dexterity. They really can't move their hands very well.

So we actually had them test with an orange, by the way, how to inject and see what was comfortable for their hands to develop our device.

Q. Okay. So one of the ways you can inject Humira is you get a little pinch of skin and inject yourself, correct?

A. Yes, that's correct.

Q. And another way you can do it, to make it useful for somebody who really has severe arthritis in their hands and they can't do that, they have what is called a pin; is that correct?

A. That is correct.

Q. And is that where the patient can actually take the document -- I mean, the vial and literally just

stick it?

A. Yes.

Q. And that's called a pin --

A. Pin device, yes.

Q. -- is that correct?

A. That's correct.

Q. And how often is Humira administered?

A. Typically, every other week.

Q. And what percentage of the patients use a syringe to administer Humira?

A. Around 47, 48 percent.

Q. And how about the pin where you just stick yourself?

A. I think it's 50 -- it's about 52, 53 percent.

Q. All right.

MR. BECK: I'd like to bring up on the screen DX384, please.

Q. (By Mr. Beck) And I'll ask you whether or not Abbott has a patent on Humira.

A. Yes, we do.

Q. All right.

MR. BECK: And if we could bring up the date, the filing date. Can we blow that up?

Q. (By Mr. Beck) All right. Now, the file date is what, with respect to the Humira patent?

A. February the 9th, 1996.

Q. That's when the application for the patent was filed by Abbott?

A. That is correct.

Q. And does this patent, what we're going to call the '226 patent, disclose and claim Humira?

A. Yes, it does.

MR. BECK: Now, if we can show the inventors on this patent, please.

Q. (By Mr. Beck) I'm sorry. I misspoke. That's the '382 patent. I misspoke.

It lists various inventors, and are you listed as the lead inventor?

A. Yes, I am.

Q. And I believe there are, what, roughly 15 to 20 inventors on here?

A. That's correct.

Q. But you are named as the lead inventor.

A. That's correct.

Q. And when -- and so the '382 patent application was filed by Abbott for Humira on February 9, 1996, correct?

A. That's correct.

Q. When was the patent actually issued by the U.S. Patent Office?

A. On July 18th, 2000.

Q. All right. Now, we talked about the patent. We talked about 2000 when you had the patent. Now I want to go back and talk a little bit about what you-all had to do to get to that point.

A. Okay.

Q. And I'll just ask you pointblank, was Humira invented overnight?

A. It wasn't. Certainly not.

Q. How long did it take to actually invent Humira?

A. The whole effort and the TNF discovery spanned more than four years.

Q. And what do you first start -- what's the first step in the process? You start working on what, fully human antibodies? When did y'all start working on fully human antibodies?

A. In 1991.

Q. And then did you, after that, start working on the program that led to Humira?

A. Yes, I did.

Q. And when was that?

A. In 1993.

Q. And when was the discovery made? When was the actual discovery?

A. In the late spring 1995.

Q. And then after the discovery in April of 1995, did you then have to do preclinical trials and manufacturing?

A. Yes. The government prescribes very careful safety studies and then clinical studies. So that was undertaken after 1995.

Q. And approximately how many of your men and women at the company were involved in that effort?

A. If you're referring now to the whole manufacturing development, yeah, hundreds.

Q. Okay. And which of those phases were you, Dr. Jochen Salfeld, involved with?

A. I was involved in all of them.

Q. Let's talk a little bit about the discovery phase.

How many of your people at Abbott were involved in the discovery phase you told us about?

A. That was smaller, maybe 15.

Q. And can you give the jury some idea of approximately how much was expended in research and development in developing Humira?

A. Total amount is in the range of 1.2 billion.

Q. And do all of the drugs or medicines that you-all work on and try to develop and discover and do

clinical trials on, do they end up being successful?

A. It would be very nice for a discovery scientist, but they are not.

Q. And tell the jury approximately what percentage of these drugs or medicines that you-all work on actually end up being successful.

A. I've heard a number that between early idea and early research to market, maybe 1 percent. It's very -- not very likely to be successful. It's very, very difficult.

Q. All right. And so whenever you do have a successful project, whatever you make on that project has got to fund other research and development that you do.

A. That is correct.

Q. All right. Now, when you first started out at BASF, what was your position?

A. I was a senior scientist at BASF.

Q. And as a senior scientist at BASF, what was your primary focus initially?

A. Really lab work. I love to do lab work. I had to -- I had to hire people to work with me. I had to set up a lab, buy equipment, clean the lab bench, do a lot of good research.

Q. And where was that lab that you eventually set

up?

A. It was in Cambridge just behind MIT.

Q. And is that the facility that you worked at?

A. Yes, originally.

Q. And what was the primary mission of that laboratory when you first started there?

A. Our mission was to develop new treatments for cancer and new treatments for autoimmune diseases.

Q. And did one of the things that you were working -- was one of the things you were working on identifying genes through what is called MAK195?

A. Yes, it was. It was one of my first projects.

Q. And what was MAK195 intended to deal with, what disease, what life-threatening condition?

A. MAK195 was designed to be used in the treatment of sepsis.

Q. And sepsis is a life-threatening condition, is it not?

A. Very much so.

Q. And had the company done any work on TNF antibodies before you joined them in 1990?

A. Yes, they had. Back to the middle of the '80s, BASF started to look into antibodies to a TNF. My colleague, Achim Moller, had started to make antibodies to TNF around '85, ending in '86.

Q. All right. And Dr. Moller, that's M-O-E-L-L-E-R (sic); is that correct?

A. That is correct.

Q. Now, what is MAK195?

A. MAK195 is a mouse antibody to human TNF, but it's very sticky to TNF, binds TNF with very high affinity and can turn off the TNF.

Q. And when was it being developed?

A. Actually, by the time I joined, I think clinical studies were either on the way already or were about to start.

Q. All right.

A. So in the early '90s.

Q. And Dr. Moller is the one who created MAK195?

A. That is correct.

MR. BECK: Let's bring up DX451, please. Before you put it on the screen...

Let me just have a minute, Your Honor.

THE COURT: Sure.

(Pause in proceedings.)

MR. BECK: My understanding, it is in evidence, Your Honor.

If we can show that first part up here, the title.

Q. (By Mr. Beck) This is a patent for monoclonal

antibodies against human tumor necrosis factor, TNF, and use thereof. And one of the inventors is Achim Moller. That's your colleague.

A. That is correct.

Q. All right. And the --

MR. BECK: If we can just back off so we can see the number.

Q. (By Mr. Beck) This is what we're going to call the '024 patent. Is this a patent that is issued to Dr. Moller and others?

A. Yes, it is.

Q. And what is this for?

A. This patent describes antibody -- mouse antibodies to human TNF, which bind TNF very tightly and can turn off TNF and the clinical uses there.

Q. All right. And it shows that this patent was applied for on September 8th, 1987, by Dr. Moller and others, correct?

A. Correct. It was actually, if you look one line down, filed in Germany, the year before that.

Q. Okay. In September of 1986?

A. That is correct.

Q. Now, what disease or diseases was BASF looking to use MAK195 for back in the mid-1980s?

A. BASF had interest in investigating acute

diseases.

Q. All right. Now, when you say acute diseases, does that mean a disease of relatively short duration?

A. Yes, it is.

Q. Give us an example of that.

A. Sepsis and septic shock is such an acute disease. It's a very, very severe blood-borne infection. It can very rapidly lead to death, or it could happen within a week or two weeks. So we call this an acute disease. It's a very acute infection with an acute difference.

Q. And what is the difference between an acute condition and a chronic condition?

A. A chronic condition can last 10, 15, 20, 30 years. It's a long-term disease. Acute is very short. Doctors see you right away. Chronic diseases take a long time and have to be treated lifelong in many cases.

Q. And did you pursue MAK195 for chronic conditions?

A. They did not.

Q. And why is that?

A. Mouse antibodies tend to be recognized as a foreign element in the human body. So you can give a mouse antibody to a patient maybe once or twice or maybe three times, but you cannot give it lifelong.

Q. What happens when you try to do that?

A. It is typically recognized by -- we all have an immune system that keeps us healthy, and that immune system will recognize that mouse antibody as foreign. So when you get the injection of this mouse antibody, the first time the body can identify it as foreign. Second, third, fourth time, it mounts in response to it, and then at some point, it will reject this mouse antibody.

Q. And what happens if that rejection occurs?

A. It could be either benign, meaning that it doesn't work, or it could be a severe allergic reaction. It depends on the circumstance.

Q. Depends on the patient?

A. Depends on the patient.

Q. Now, what is an immunogenic reaction?

A. Immunogenic reaction is, our immune system that keeps us normally healthy needs to know what is ourself, what is our body, because it needs to distinguish our body from something that invades our body.

So it is learned. When we are young, it learns who we are and what we are made of, and then if something foreign invades our body, it recognizes that, and then that is an immunogenic reaction, if the body

then responds to that foreign agent.
It could be a virus; it could be a bacteria; could be a mouse antibody.

Q. And did you identify any other medical indications besides sepsis that related to TNF-alpha?

A. Yes, we did.

Q. What were they?

A. A graph -- it's an example on the graph of a source disease. But Achim Moller also did some further investigation, looked at other diseases. So he identified -- he actually put together a test system to look at the levels of TNF in patients, and he looked at which disease is characterized by what level of TNF.

And he found that patients with arthritis have a high level; the patients with transplant rejection, a very high level; sepsis is very high level and so on.

So he identified a number of different diseases that are characterized by very high levels of TNF.

Q. And we talked about MAK195. Did MAK195 ever go to market?

A. It did not.

Q. Why not?

A. Clinical trials in sepsis are very, very difficult, because patients have sepsis for very

different reasons. Sometimes it's a hospital-acquired infection. Sometimes it's a gunshot wound; it's an injury.

And all of these diseases look like sepsis. They have very high mortality. But it appears that a single drop may not be enough to treat that. So we did clinical trials, very large clinical trials.

There's a small difference between the placebo group and the MAK group, but the FDA did not think that that difference was large enough to approve it as a new therapeutic for sepsis.

Q. All right. You used the term placebo group. That's where you do testing, and one control group is given, for example, MAK195. The other group is given something that is supposed to have no effect at all.

A. That is correct.

Q. And you compared the two?

A. That is correct.

Q. Okay. And after all of the work that was done and all of the research and all of the time and expense that was incurred, the bottom line was that MAK195 never went to market.

A. That is correct.

Q. At some point, Dr. Salfeld, did you become involved in a project to develop a fully human antibody?

A. Yes, I was.

Q. All right. We talked about MAK195 and it being a monoclonal mouse antibody.

Now you're going to work a fully human antibody.

A. That's correct.

Q. Why were you doing that?

A. I mentioned earlier that a mouse antibody cannot be used for the long term in patients, and we wanted to do something that had not been done before. So we wanted to develop a new class of therapeutics, come up with a fully human antibody that we assumed could be given for a long time to patients.

Q. All right. And when did you start trying to develop a fully human antibody?

A. In 1991.

Q. And what type of fully human antibody did you set out to develop?

A. We wanted to develop a high affinity, very sticky -- that it combined TNF with high stickiness, and that way it can turn off TNF.

So fully human antibody that sticks very well to human TNF, and it can turn off human TNF.

Q. All right. So what you're looking for is a fully human TNF antibody that has two components.

One is called high affinity.

A. Correct.

Q. And the other one is called neutralization.

A. That is correct.

Q. And high affinity means stickiness, right?

A. Stickiness.

Q. And what you're looking for is a fully human antibody that will actually stick, correct?

A. That is correct.

Q. Stick to the TNF.

A. Stick to the TNF.

Q. And if it sticks to the TNF, then that's when you get neutralization.

A. If it sticks to TNF at the right place, you get neutralization, yes.

Q. And when you get neutralization, what does that do to the TNF culprit, if you will?

A. It can safely move out of the body, and in the meantime, prevent it from doing its disease-causing effect, thereby helping the patient to heal.

Q. And what -- what was the first step -- and by the way, did you and your team isolate a fully human TNF antibody?

A. We did, in collaboration with Dr. Casali at NYU.

Q. All right. Let's talk about Mr. Casali. Who is Dr. Casali? That's C-A-S-A-L-I.

A. Dr. Casali is a very, very, very respected professor at that time at New York University in New York, was a specialist in a certain method to make human antibody.

Q. All right. And this method, did this involve human B-cells?

A. Yes, it did.

Q. And does each B-cell -- human B-cell produce one antibody?

A. Yes, it does.

Q. And what is the effect of that?

A. All of us have millions of antibodies in our body, and each piece makes one antibody.

Q. Okay. And what was the goal of this collaboration with Dr. Casali?

A. The goal was a fully human antibody that sticks to TNF very tightly and turns off TNF.

Q. And did you have a contract -- or did Abbott have a contract with Dr. Casali?

A. Yes, we did.

Q. And what technology were you using in connection with this collaboration with Dr. Casali?

A. The technology involved the isolation of human

B-cells on patients, and then the immortalization of these B-cells, a process to make these B-cells live longer.

Q. And why do you want these human B-cells to live longer?

A. In our body, the B-cells typically live just a short time, at least most of them, and if you take them out of the body into the lab, they can die very quickly. So you have to make them live longer so you can do studies in identifying which of these B-cells makes the correct antibody.

Q. And how long did this collaboration with Dr. Casali last?

A. A little bit more than two years.

Q. And what was the result of that collaboration?

A. Unfortunately, it failed.

Q. And why did it fail?

A. They identified human antibodies to TNF that bound to some extent, not high enough, but it did not turn off TNF. So we had not met the three goals we set to ourselves.

Q. So at this point, which was taking you up to, what, late 1993?

A. '93, yes.

Q. MAK195, a lot of work done on that, correct?

A. Yes.
Q. It was not successful.
A. Not successful.
Q. Then you had your collaboration with Dr. Casali.
A. Yes.
Q. Spent additional time and work and resources.
A. Yes.
Q. And the result of that unsuccessful.
A. Unsuccessful.
Q. Now, aside from this human B-cell approach with Dr. Casali, did you consider any other technologies in this pursuit of a fully human TNF antibody?
A. Yes, we did.
Q. And who was that collaboration with?
A. We explored a collaboration with two other companies. One was Cambridge Antibody, and the other one was a company called GenPharm.
Q. All right. So you considered two options.
A. We did.
Q. And which option did you go with?
A. We opted to work with Cambridge Antibody.
Q. And why did you opt to work with Cambridge Antibody?
A. Cambridge -- we knew that this project and the

other experiences with this project, it would be very, very difficult. So we looked at a company which had technology but also had very, very good scientists.

And Cambridge Antibody had a very famous professor, Sir Professor -- Professor Sir Greg Winter, as part of the leadership team. He has revolutionized the antibody technology with a number of key inventions. And we thought if he worked with Cambridge Antibody and Professor Winter was in the background, this would give us a very good starting point for such a challenging project.

Q. All right. One of the witnesses called to the stand by Centocor referred to a technique known as the phage display.

Is that the technology employed by Cambridge Technology?

A. It is, yes.

Q. And that witness also said that a phage display is like looking for a needle in a haystack. Do you agree with that?

A. I do not. Actually, I would say it's a needle in a field of haystacks.

Q. Now, was the phage display technology that you opted to go with, with Cambridge, was that very early in its development as well?

A. It was, yes.

Q. Had CAT or Cambridge ever made a fully human antibody before?

A. They had what they call binders, low-affinity antibodies that can recognize different other targets. They had never made a high-affinity neutralizing therapeutic antibody before.

Q. All right. What made you think, Dr. Salfeld, that a collaboration with Cambridge was any more likely to succeed than MAK195 or the technology you employed with Dr. Casali?

A. Obviously, if you want to do discovery research, you have to be optimistic. You have to try different things.

We heard about two that failed. You have to be optimistic, have a good goal in mind, and what you really want to do is to be patient till the end.

So we tried lots of different things, and we thought phage display with the team at CAT with Professor Winters in the background might be worth trying.

Q. Okay. And when did the collaboration with Cambridge begin?

A. In early 1993.

Q. And just so the jury might know, Cambridge,

we're talking about in England; is that correct?

A. Cambridge in England, yes, UK.

Q. All right. And what was the state of this phage display technology when the collaboration between Abbott and Cambridge began?

A. Phage display was still in its early technology development phase. People were developing new methods to do phage display. As mentioned earlier, that CAT and others had developed antibodies, you know.

But to my knowledge, there was no therapeutic antibody developed with that method at that time.

Q. All right. Did I ask you to prepare -- to assist me in preparing some slides to explain your scientific work?

A. Yes, you did.

Q. All right.

MR. BECK: If we may bring up on the screen the phage display.

Q. (By Mr. Beck) Now, before we get to the specifics here, what were you trying to do with this phage display collaboration with Cambridge? What was your objective? What were you trying to -- what were you trying to get?

A. We were trying to develop a fully human antibody that sticks to TNF-alpha, that turns off

TNF-alpha.

Q. And were you ultimately successful in generating a fully human, high affinity, neutralizing antibody to TNF?

A. After a lot of very hard work, yes, we were.

Q. And what was that antibody?

A. D2E7, which then became Humira.

Q. And we've used the word discovery here, and I want to make sure that we're all together on what we mean by discovery.

When was Humira discovered?

A. The big eureka moment was in April 1995. So it's in that timeframe, April, May, 1995.

Q. Now, when you say eureka moment, is that, you know, we did it?

A. Yes.

Q. I mean, is that what you're talking about?

A. Yeah, we did it.

Q. All right.

A. Finally, we got to the goal.

Q. And that was when?

A. April/May 1995.

Q. And how long was that after the collaboration with Cambridge began?

A. It was a little bit more than two years.

Q. And how much -- approximately how many antibodies did Abbott and Cambridge in their collaboration create before this eureka moment when you say, we've done it, we've done it?

A. Hundreds or maybe even thousands.

Q. All right. Now, let's go to the phage display slides that we've talked about.

Now, what does this depict here?

A. If you want to develop a fully human therapeutic antibody, you have to start with human building blocks. All of us have antibodies in our body, so we have to start getting those building blocks from our bodies.

We started with human volunteers.

Q. All right. So you start with people. And then what's the next step?

A. You have to take the genetic information.

Q. And you get that genetic information from whom?

A. From these volunteers, from their B-cells or cells that produce antibodies.

Q. All right. And then what's the next step?

A. The next step is to isolate those genes that can make the antibody.

Q. And is that something easy to do?

A. It's not that easy. We mentioned earlier that the body has about 25 to 30,000 genes. All we have to do now is pick all the genes that make antibodies but not the other 29,999 genes.

Q. So you've got to find that one in that group of haystacks.

A. Yeah.

Q. All right. Now, after you get the genetic information from humans and you get the genes that make the human antibodies, what do you do next?

A. Rearrange them. You've heard already that antibodies consist of a heavy chain and a light chain. So there are two genes for each antibody.

So to create a very large library or collection of antibodies, we have to now take all the heavy chains and mix them with all the light chains.

That's exactly the way the B-cells in our body make antibodies, by, at random, combining a heavy chain with a light chain. This method can do this in a test tube.

Q. Okay.

A. So we rearrange the antibody genes.

Q. And is -- that rearranging of the genes, is that something that's easy to do?

A. It's not.

Q. Does it take a long time?

A. We were working at that time with Cambridge Antibody, one of the world leaders in phage display technology.

Q. All right. Now, after those four steps, what's next in line?

A. Now we have to select the antibodies out of this library that bind TNF-alpha. And that is like looking for a needle in a field of haystacks.

When I was driving over to Marshall, I saw somebody baling hay with the big round hay bales. Think about a big field of hay bales, and one of them has a needle in it and finding that needle. It's going to be very, very difficult. That's exactly the complexity here.

Q. All right. All right. Now, after you select the antibodies that bind the TNF-alpha, what question are you trying to answer here?

A. Let me briefly tell you how that actually is selected.

Q. All right.

A. The selection is very complicated, because you have a million different antibodies or more, and you have to find the one in that one haystack.

Think about it, if I have a ring with keys, in

order to open my home door, I always get confused which key is the right one. Think about you have a ring with a million keys on it, and you have to find the one key that fits into that lock. Because antibody antigen interaction is like a key in a lock.

So now you have to -- you can either try all these million keys one at a time in your lock, or phage display is designed to have the lock actually help you find which of these million keys is the one. And that's the way we do that TNF selection.

Q. All right. And then after you make that selection, the question you're trying to address is what?

A. The goal was a very sticky antibody that sticks to TNF and do nothing else and turns TNF off. So the question is, does the antibody have a strong grip at the right place on the human TNF-alpha?

Q. If it doesn't have a strong grip, it's not going to work, is it?

A. It's not going to work.

Q. If it's got a strong grip, but it doesn't bind or stick in the right place, it's not going to work, is it?

A. It's not going to work.

Q. Now, what tests do you do to answer the

question of whether or not the antibody has a strong grip in the right place?

A. We have two scientific tests for that. One is a test for stickiness. And you can think about this as if you have a Post-It Note. You know, you can -- you can -- it sticks, but I can rip it off. It's a very low affinity.

Think about that with Super Glue. With Super Glue in between here, I can't get it apart. So you want to be on the side of the Super Glue and not on the side of the Post-It Note.

So the test is looking at is your antibody sticking to the TNF more like that Super Glue and not like a Post-It Note.

And the second test is just looking at can we turn off TNF with that antibody.

Q. All right. Now, after you tried to address that question and ran the test to test for stickiness and whether or not you were going to be able to turn off the TNF antibody, tell the jury whether or not that worked.

A. It did not.

Q. So this was the third effort that you made and it didn't work.

A. Did not, yes.

Q. So what did you do next, Dr. Salfeld?

A. A lot of thinking, a lot of thinking about what we could do next, and then we employed a variant of phage display, which we call guided selection.

Q. And who came up with this guided selection?

A. It's a technique that Cambridge Antibody had been looking into as a possibility for antibody generation.

Q. All right. And so you're now employing a different technique, guided selection.

A. Yes, we do.

Q. And after you employed guided selection, tell the Ladies and Gentlemen of the jury what the result was.

A. After a lot of further hard work -- guided selection is like going from that field of haystacks to one haystack, and you still have to find the needle or antibody in there.

So it's still a lot of work finding the right antibody, but at least we were successful at that point.

Q. So you've narrowed it now to at least one haystack.

A. We did.

Q. All right. And after you employed guided selection and after a lot of additional hard work, did

you eventually reach the point where what you had been working on for years, four to four and a half years, became successful?

A. We were successful, yes.

Q. And when was that?

A. April, May 1995.

Q. Now, the jury's heard a little bit about this. Has Humira been a successful product?

A. Yes, it has.

Q. And approximately how many patients have taken Humira?

A. Around 300,000 patients worldwide.

Q. Now, are you aware that there have been a number of letters that have been written in to Abbott from patients who have benefited from the research by you and your colleagues?

A. Yes. Patients have sent thank-you letters to Abbott.

Q. And are some of those letters actually displayed in the headquarters of Abbott?

A. Yes, they are.

Q. And, frankly, you personally, have you even had patients ask to have their picture taken with you?

A. Yes. I had that experience. I had a young mom come to me who was using Humira. She was telling

me, I wanted to be a mom; I had three kids. I believed I couldn't be the mom I wanted to be. I took Humira and I could again be the mom that I always wanted to be.

But she had been unable to be with her kids or helping her kids for years prior to Humira. And she was so thankful, so she said can we take a picture together. And we took a picture together.

Q. Let me just ask you, how does that make you feel?

A. I'm very happy for that mom and that family that they have their life back. We keep hearing from patients that we want our life back, and they do get that with a drug like Humira.

Q. And how does that make you personally feel when it helps people like that?

A. Very thankful to have been a part of generating that drug. And I'm still thinking about my grandmother who died so many years ago. She only had -- I don't even know what treatment she had at that time, but it came too late for her.

Q. All right. Now, the jury's heard a little bit about this, the Galien Prize. Mr. Lee made me hold this up without any advance notice.

MR. LEE: You want me to hold it up?

MR. BECK: Yeah, would you hold it up,

please?

Q. (By Mr. Beck) And you're aware that Abbott received the Galien Prize for its invention of Humira.

A. Yes, I do. I am.

Q. And when was that?

A. There was a big gala in September 2007 in New York City.

Q. All right.

MR. BECK: Can we bring up on the screen Exhibit 759, please?

And if we could look at the page ending in the Bates Nos. 71 -- hold on just a minute -- Bates numbers ending in 6713.

All right. Back up.

Q. (By Mr. Beck) Now, according to this exhibit --

MR. BECK: Which is in evidence, Your Honor.

Q. (By Mr. Beck) It says the Galien Prize is considered the industry's equivalent of the Nobel Prize and the highest accolade for biopharmaceutical research and development.

How did it make you feel when Abbott received what effectively was the Nobel Prize for biopharmaceutical research?

A. It was a recognition for a lot of hard work by an excellent team.

MR. BECK: And if we could look at the page ending in Bates No. 686.

Q. (By Mr. Beck) That lists the committee, does it not, that was -- the Galien Prize U.S. Committee that actually named Abbott to receive the Galien Prize?

A. Yes. That's that list, yes.

Q. All right. And I don't know if the jury can see this or not.

MR. BECK: Is there any way we could --

Q. (By Mr. Beck) There's a name on here, Dr. Jan Vilcek. Are you familiar with --

A. I can see that.

Q. -- Dr. Jan Vilcek?

A. Yes, I am.

Q. And who is he?

A. Dr. Vilcek is a professor in New York, and he is a co-inventor on the Centocor '775 patent.

Q. All right.

MR. BECK: And if we'll look at the Bates -- the page ending in Bates No. 703.

Q. (By Mr. Beck) It says -- it's got Dr. Jan Vilcek's name on here as co-inventor of Remicade. Do you see that?

A. I see that, yes.

Q. So we have Dr. Jan Vilcek who was the co-inventor of Remicade that is applauding -- applauding the Galien Prize USA Committee for stressing the importance of humanism through its Pro Bono Humanum Award, correct?

A. That's correct.

Q. And then if we go up a little bit, it goes on to say: We congratulate today's honorees, salute the distinguished members of the Review Committee, including two prominent members of our faculty.

Is that correct?

A. That is correct.

Q. And isn't it a fact that several of the Galien Prize committee members are also on the committee to award the actual Nobel Prize?

A. There are number of actual Nobel Prize winners on that committee.

Q. Okay.

MR. BECK: Now, if we can put up the '775 patent, which I believe is PX1, and if we can focus in on who the inventors are.

And this is the '775 patent.

Q. (By Mr. Beck) And up on top, you'll see Dr. Jan Vilcek's name as the second person listed on the

'775 patent.

A. I do see that.

Q. Okay. Now, I want to go over some key dates and then I'm finished. And then they get to question you.

MR. BECK: If we can bring up -- I'm going to go through some dates, and if we can bring up the dates as I go through these so the jury can see them.

Q. (By Mr. Beck) Doctor, when was MAK195 antibody isolated?

A. 1986.

Q. When did Abbott start its collaboration with Dr. Casali?

A. 1991.

Q. When was Humira discovered?

A. 1995.

Q. And when was the CAT collaboration?

A. The CAT collaboration started in 1993.

Q. So you had the MAK195 discovery in 1986; you have the Dr. Casali collaboration '91 to '93; you have the CAT collaboration or the Cambridge collaboration on phage display '93 to '95.

A. Yeah.

Q. Then in April of 1995, you have what you

called a eureka moment when you all said we've done it, correct?

A. Exactly. Exactly.

Q. Now, when was the patent application for Humira filed?

A. 1996.

Q. And when was the first clinical trial of Humira?

A. 1997.

Q. And when was the '382 patent on Humira issued?

A. The year 2000.

Q. And when did Abbott file for FDA approval of Humira?

A. In early 2002.

Q. When did Abbott receive the FDA approval for Humira?

A. It was received in 2002.

Q. When did Abbott start making Humira?

A. It started selling Humira in early 2003.

Q. Now, the jury has seen a copy of Centocor's '775 patent, and it was filed on July 18, was it not?

A. 2002.

Q. July 18 --

A. 2002.

Q. -- 2000 (sic)?

A. Yes.
Q. And when was it issued by the --
A. 2006.
Q. -- PTO?
Did Abbott or Centocor file their patent application first?
A. Abbott did.
Q. Did Abbott or Centocor receive its patent first?
A. Abbott did.
Q. In fact, this timeline shows, does it not, Dr. Salfeld, that Abbott received a patent for Humira before Centocor even filed their '775 patent application? Does it not, sir?
A. That is correct.
MR. BECK: Pass the witness, Your Honor.
THE COURT: Ms. Elderkin.

CROSS-EXAMINATION

BY MS. ELDERKIN:

Q. Hello, Dr. Salfeld. Nice to see you again.
A. Same here.
Q. I think we last met at your deposition in January.
A. In Washington, D.C., yes.
Q. I think it was about a hundred degrees cooler,

if I remember.

A. It was a very nice day. It was shortly after the inauguration, if I remember.

Q. Right. I think it had warmed up a little bit from the inauguration, but a little bit cooler than that today here.

Dr. Salfeld, congratulations for your contribution to Humira. And the Galien Award was actually for the drug Humira, not for any particular -- not awarded to any particular individuals, correct?

A. That's totally correct. It was given to the drug, not to me, not to -- to Abbott for the drug, yes.

Q. Just as Remicade had been awarded the Galien Prize several years earlier, correct?

A. Exactly.

Q. Okay. Now, the decision to develop a fully human antibody against TNF-alpha wasn't made at BASF Pharma until 1992, after Bob Kamen had come, correct?

A. It was actually in 1991.

Q. Okay. Well, let's -- do you have in your binder Plaintiffs' Exhibit 80?

MS. ELDERKIN: And before you put it up, can my team confirm, is that in evidence, PX80?

Yes, it is.

If you could put it up on the screen, Mr.

Ficocello.

Q. (By Ms. Elderkin) Do you recognize Plaintiffs' Exhibit 80, Dr. Salfeld?

A. I have seen that, yes. And I open to 80?

Q. 8-0.

A. 8-0, yes, I have it. No problem.

Q. Okay. And you recognize that as a memorandum that you drafted at Abbott in January of 1994?

A. Let me look.

Yes, it is. Yes.

Q. Okay. And if we could -- if you could look at the first full page of text; it's the page that ends 772 in the bottom right-hand corner.

MS. ELDERKIN: Mr. Ficocello, if you could put that up and highlight the first paragraph.

Q. (By Ms. Elderkin) In 1994, you wrote that BASF Pharma decided during 1992 to develop a fully human antibody against TNF-alpha, correct?

A. Yes, but this must be a mistake, because we started in '91, the Casali collaboration started in 1991.

Q. Well, at least in 1992, you started evaluating available technologies for making a human antibody, right?

A. As I have said earlier, we had started working

on the Casali project in 1991. In '92, we looked at additional technologies.

Q. And one of those additional technologies was the antibody gene library in phage display. You talked about technology offered by CAT, Cambridge Antibody Technology, right?

A. Yes.

Q. And in 1991, you attended a number of exploratory meetings with CAT, right?

A. Yes, I did.

Q. And at the time, CAT was actually looking for business partners. They were looking for companies they could collaborate with to make human antibodies, right?

A. That's correct.

Q. In fact, they were even advertising in scientific journals.

A. That's correct.

Q. We would like to collaborate with you and make human antibodies for you.

A. That's correct.

Q. Because CAT needed payments from other companies to fund its work, right?

A. That is correct.

Q. So in September 1992, you understood that CAT had, quote, long-standing experience with its approach

for creating human antibodies, didn't you?

A. No. What I knew was that CAT had -- was working in phage display space, and they were working on technology development, more basic technology development, not actually draw up discovery applications of that technology.

Q. Okay. Could you look in your binder, please, at Plaintiffs' Exhibit 78?

MS. ELDERKIN: And could we confirm that that is admitted?

Mr. Ficocello, would you put up the first page of Plaintiffs' Exhibit 78, please?

Q. (By Ms. Elderkin) And do you recognize this as a memorandum you wrote in September 1992, Dr. Salfeld?

A. Yes, I do.

Q. Okay. And if you could look -- there's a statement towards the bottom of what's shown on the screen here. It says: CAT has long-standing experience with their approach that reproduces the human immune response by random assortment of human heavy and light chains and the selection of the best binders, using a phage display method.

And you wrote that in 1992, correct?

A. That is correct.

Q. You wrote that CAT had long-standing

experience with their phage display technology.

A. Yes, that is correct. And they had been working in this phage space on technology development for a number of years. That's totally correct.

Q. You also said in this paragraph that the method Cambridge -- CAT's method has -- and this was in 1992 -- has been used for a variety of antibodies, most recently a non-neutralizing TNF-alpha antibody from Peptech, correct?

A. That is correct.

Q. And in addition to that TNF antibody that you referred to in your memo here, CAT actually told you in October 1992 that it had already identified some human antibodies that might neutralize TNF, right?

A. No, they did not. I mean, they had done some -- as I said in my direct, they had --

THE COURT: Now, Doctor, the question was simply this:

A. No.

THE COURT: Did they tell you that or not?

A. They did not.

Q. (By Ms. Elderkin) Okay. Would you look in your binder, please, at Plaintiffs' Exhibit 745?

MS. ELDERKIN: And this is not admitted,

so we don't want this up, please.

Q. (By Ms. Elderkin) Do you recognize Exhibit 745 as a witness statement that you gave in another legal proceeding?

A. Yes.

Q. Okay. Would you look at Paragraph 62, please?

A. 60 -- you're talking about the paragraph, right?

Q. Numbered paragraphs, 62, right.

And you agree that in that paragraph in the third sentence, you said: More importantly for the purposes of our collaboration, in a fax dated October 5, 1992, CAT has also told us that they had identified some antibodies that might neutralize TNF.

And that's what you said in your witness statement in the other legal proceeding, right, Dr. Salfeld?

A. That is correct, but I did not --

THE COURT: Doctor, now we're going -- we're not going to do this. You have been in the courtroom the whole time. You know what the rules are.

All right. Thank you.

Q. (By Ms. Elderkin) And October of 1992, CAT also assured you that its gene libraries were a proven source of TNF-alpha antibodies, didn't they?

A. Yes. They said they were -- yes.

Q. Okay. And as of September 1992, CAT had available a library of an unprecedented number of clones available for screening; isn't that right?

A. I believe that's what they said, yes.

Q. In fact, you reported in that memo, Plaintiffs' Exhibit 19 -- Plaintiffs' Exhibit 78 --

MS. ELDERKIN: If you would put that up again, please.

If you could scroll down onto this heading, please, Mr. Ficocello.

Q. (By Ms. Elderkin) Is that what you said in this September 1992 memo was: Currently, a library of unprecedented 10 to the 23rd different clones, i.e., heavy/light chain combinations, is available for screening, right?

A. That's what I said.

Q. And 10 to the 23, that's like 10 with 23 zeros after it, isn't it?

A. Yes, it is.

Q. That's even more than the billions we've been hearing about today, correct?

A. That is correct.

Q. And as of September 1992, CAT had already successfully humanized murine antibodies, hadn't they?

A. It was one antibody I'm aware of.

Q. Okay. Let's look at the second page of this memo, please.

MS. ELDERKIN: Under the heading, Humanization of Murine Antibodies, if you could blow that up, please.

Q. (By Ms. Elderkin) And there's a statement there in your memo: CAT has successfully humanized murine antibodies and was able to keep and even improve the binding affinities, correct?

That's what you reported in your September 1992 memo?

A. Yeah.

Q. In fact, in September of 1992 when you wrote this memo, you believed the CAT's approach for creating human antibody was proven, correct?

A. That's correct.

Q. You say that in this memo, right?

A. I said that, yes.

Q. And you don't recall CAT ever expressing to you that it had any doubts about whether it would be able to meet your research goal of coming up with a high-affinity neutralizing anti-TNF antibody, correct?

A. I don't recall that, yes.

Q. Now, it turns out that BASF -- and it was BASF

you were working at at the time; it wasn't Abbott yet, correct?

A. That is correct.

Q. Abbott came and purchased BASF in 2001?

A. Yes.

Q. Okay. So it turns out that BAS -- BASF didn't actually sign an agreement to start collaborating with CAT to develop a human anti-TNF antibody until August 1993, correct?

A. That is correct.

Q. Okay. And that -- August 1993, that was after you at BASF had heard about the remarkable results that had been found in Centocor's testing of the cA2 antibody in rheumatoid arthritis patients, right?

A. The work actually started in early '93. The actual research work preceded signing the contract. So we were actually working on this program already in early 1993.

Q. And it was in March 1993 that you heard about the remarkable results that Centocor's cA2 antibody in rheumatoid arthritis patients were showing, correct?

A. That is correct.

Q. And you -- personally, you thought that those studies -- and they were Dr. Feldmann's studies in London -- those studies of the Centocor cA2 antibody

demonstrated remarkable efficacy of the Centocor antibody, correct?

A. That is correct.

Q. And you understood that -- this report of patient testing of Centocor cA2 antibody in rheumatoid arthritis patients, you understood that to be the first actual confirmation that anti-TNF antibodies could have therapeutic utility in rheumatoid arthritis, right?

A. Yes.

Q. And that was a good thing, right? Because as you testified earlier today, the first part of drug discovery is figuring out what actually causes a disease, right?

A. Correct.

Q. And it's one thing to theorize that TNF might cause rheumatoid arthritis. It's another thing to actually see the antibody administered to humans and see that it actually works to help patients with rheumatoid arthritis, right?

A. That's correct.

Q. And Centocor was the first to do that with any anti-TNF antibody, correct?

A. Yes.

Q. And that was nice confirmation for BASF as they were just embarking on this project that would

ultimately -- they would ultimately spend hundreds of millions of dollars on it. It was nice for them to have that confirmation from Centocor's work that they were going down the right track, correct?

A. Yes. It confirmed what we had been working on for years, yes.

Q. So as I think you just said, it was sometime in spring/early summer of 1993 that you actually started working with CAT --

A. That is correct.

Q. -- using its phage display technology in the TNF project, right?

A. Correct.

Q. And you used the MAK195 antibody as a starting point to guide the selection of the heavy and light chains -- the human heavy and light chains?

A. Yes.

Q. And that's the technology you described as guided selection, right?

A. Exactly.

Q. Okay. Another term for that is epitope implanting; is that right?

A. Imprinting.

Q. Imprinting. Okay. Thank you.

And then CAT also used something called

affinity maturation to improve the affinity of the lead candidate antibody fragments, didn't they?

A. Yes, they did.

Q. And by 1994, you had a fully human antibody that you called 2SD4, correct?

A. That is correct.

Q. That was just a little bit over a year after you actually started working with CAT in this collaboration, right?

A. I'm just trying to add together -- yes, about that.

Q. And 2SD4 actually had pretty good affinity, didn't it?

A. It had some good affinity characteristics, but the operate, unfortunately, was poor.

Q. But its affinity, its Ka, its association -- its Ka, association constant affinity, was over 10 to the 8th, wasn't it?

A. It was.

Q. And it also was a neutralizing antibody, wasn't it? Neutralized TNF?

A. Yes.

Q. So a little bit over a year from when you started working with CAT on the phage display, you had a human anti-TNF antibody, a recombinant human TNF

antibody that had an affinity of at least 10 to the 8th and that was neutralizing, correct?

A. That is correct.

Q. Now, 2SD4 was a precursor for D2E7, right?

A. That is correct.

Q. Okay. You just made 2SD4 even better for Humira?

A. Yeah. We wanted to make the best draft we could to make it better, yes.

Q. And the whole drug discovery process for Humira, the time from when you started working with CAT until you actually had the Humira antibody, not just the 2SD4 antibody, the whole process took about two to two and a half years, right?

A. That is correct.

Q. And that's not unusual. That's not an unusual time -- length of time for a successful drug discovery process -- project, is it?

A. That is correct.

Q. In fact, you've worked on other drug discovery projects at Abbott, and two and a half years is not at all unusual, right?

A. That is correct.

Q. Because nothing happens quickly in this science, does it?

A. Everything is very, very hard work, yeah.

Q. You talked a little bit about your patent, Dr. Salfeld. And you filed the first patent -- the first patent application on this human anti-TNF antibody in 1996, right?

A. Yes, we did.

Q. You had a number of co-inventors, correct?

A. Yes.

Q. And Zehra Kaymakcalan was one of your co-inventors?

A. Yes.

Q. And since that original 1996 application was filed, you've actually refiled the application a number of times, correct?

A. Yes.

Q. And that's not at all unusual in this field, is it?

A. No, it is not.

Q. You have a first invention; you disclose it in your application. Sometimes you learn some new things; you file the application again. You add some additional information as you learn it.

A. That's the way I understand it. I'm assigned to -- I am not a patent attorney. The way I understand it is that the -- when I make a filing to the Patent

Office, I disclose everything I know about the project at that time. Then the Patent Office issues what's called restriction requirements.

So I can only give you a patent on part of your invention. And then I file a CIP to keep that patent alive to then claim the next invention. Maybe one can get a patent on the DNA for the antibody. The next patent may be the protein, and the next patent may be the therapeutic use.

But I'm not aware that you can keep adding stuff to a CIP.

Q. We'll let the Court instruct the jury on those intricacies of patent law.

But you do understand that it's not uncommon to continue to file a series of applications after a first application.

A. Yes.

Q. And to get a series of patents based -- stemming from an original first filing.

A. Yes.

Q. In fact, that's happened for you, correct?

A. Yes, it has. Yes.

Q. And you still have some application -- even though your first application was filed in 1996, now in 2009, you still have some applications pending in that

same chain of applications before the Patent Office, correct?

A. I believe so.

Q. I'm sorry. We'll try not to talk over one another.

A. I apologize.

Q. Me, too. We're driving the court reporter nuts, I'm afraid, even though we're trying to talk slowly.

Now, the claims in your patent, you said your patent covers Humira, correct?

Are your claims limited to Humira? Is that the only antibody that's covered by your patent?

A. Again, I'm not a patent attorney.

Which patent?

Q. I'm sorry. It's Defendants' Exhibit 384.

A. 384.

Q. It's in either one of the binders, I believe.

A. Yeah, it's next -- yes. Claim 28 claims D2E7 or Humira.

Q. Right. Right.

But the other claims in your patent cover antibodies in addition to Humira. Is that your understanding?

A. I think they cover variants of Humira.

Q. Okay. You don't think that they would cover anything other than a variant of Humira?

A. I'm not a patent attorney.

Q. Okay. Do you disclose how to make any antibodies other than Humira in your patent?

A. Yes, we do.

Q. Just variants of Humira, though, correct?

A. No. We have teachings on other methods of making human antibodies.

Q. Okay. I wasn't precise enough.

Do you disclose any -- do you have any actual examples disclosing how you made antibodies other than Humira or its precursors in this patent?

A. No.

Q. Do you have any examples showing how to make Simponi in this patent?

A. No. We have disclosed how --

Q. Dr. Salfeld --

A. No.

Q. Just answer my question. Thank you.

And do you understand that it's not necessary that a patent provide a working example of every single antibody that might be covered by the claims?

A. I apologize. I'm a scientist. I don't -- I can't answer the question.

Q. Okay. And do you understand that the fact that you or Abbott has a patent on Humira is no defense to a possible claim of infringement under Centocor's patent?

A. That is my understanding.

Q. Because you can still infringe another patent, even though you have your own patent.

A. That's my understanding.

Q. In fact, Abbott even pays royalties to some other people who have patents for Humira, correct?

A. That's correct.

Q. Okay. You talked a little bit about the mouse antibody, MAK195.

A. I did, yes.

Q. And that a potential problem with a mouse antibody is that the human body would see it as foreign and make antibodies against it, correct?

A. Yes.

Q. Well, that can happen even with what you call a fully human antibody like Humira, can't it?

A. Yes, it can.

Q. Because even though we call it fully human, it really doesn't exist in any of our bodies naturally, correct?

A. That's correct.

Q. And, in fact, as Dr. Hoffman testified, Abbott's Dr. Hoffman testified on the videotape this morning, Abbott does not represent to anybody that Humira is less immunogenic than Remicade, a chimeric antibody, does it?

A. We do not.

Q. Because it can't make that representation, right?

A. The FDA does not allow comparative statements like that.

Q. I'm going to switch to the ELMO for a minute, DocCam.

You're not a patent lawyer, Dr. Salfeld, and I'm not a technical person.

Let's look at the timeline that you talked about.

MS. ELDERKIN: This takes better orientation than I've got.

THE COURT: If you can back it off a little and get the autofocus there.

Mr. Smith?

MS. ELDERKIN: Thank you. If there's a way we can get the whole thing on, that would be great. Beautiful. Thank you.

Q. (By Ms. Elderkin) Let's just talk about a few

dates that aren't on this timeline, if we could. 1993 is when you said you and BASF learned about the cA2 clinical results in rheumatoid arthritis patients, right?

A. Yes.

Q. Okay. And you know that in February 1994, you were here in the courtroom when Dr. Ghrayeb, who's one of the inventors of Remicade, testified, right?

A. Yes.

Q. And you heard him testify that in February of 1994, Centocor filed a patent application in which it disclosed human antibodies, correct?

And he talked about adding a disclosure about phage display and a citation to Dr. Marks' 1993 article.

A. I remember, yes.

Q. So that 1994 application was before Humira's, your patent application, was filed in 1996, almost two years earlier, correct?

A. That's correct.

Q. And by 1994, you had 2SDS?

A. 2SD4.

Q. 2SD4. And that was a high-affinity neutralizing anti-TNF antibody. It only took you about a year to get there working with CAT.

A. Something like that, yes.

Q. And in 1998, you heard Centocor got its first approval for Remicade.

A. I'm sure I heard that. I don't remember a year now, but if you tell me it was 1998, I believe you, certainly.

Q. And you heard that in 1999, Remicade was introduced, right?

A. Yes.

Q. I apologize for my very sloppy writing. I think we got the point.

So you would agree with those additions to your timeline, correct?

A. Yes.

Q. Thank you.

MS. ELDERKIN: Pass the witness.

MR. BECK: We have nothing, Your Honor.

THE COURT: All right. You may step down, Doctor.

Ladies and Gentlemen, I think we'll go ahead and break for the day rather than start with a new witness at this hour.

Remember my instruction about not discussing this case with anyone or allowing them to discuss it with you. That's very important.

It's very important to not try to do any

research, search the internet, or anything like -- any type of research of any kind.

And like I've said before, I don't know what will be in the newspaper, but I'm always surprised what is or is not in there on the cases that are being tried here. But do not read any articles or listen -- or allow yourself to listen to anything on the television.

Decide this case solely upon the evidence. Keep in mind my prior instructions. You know, you're just now beginning to hear from the other side through their witnesses, so it's important that you keep an open mind throughout this trial.

With those instructions, I release you. And drive safely, and I'll see you in the morning, and we'll get started at 8:30. Thank you.

COURT SECURITY OFFICER: All rise.

(Jury out.)

THE COURT: All right. Be seated, please.

Are you ready to go forward, Mr. Lee, with your motion, or do you need a break?

MR. LEE: No, no. I'm fine, Your Honor.

THE COURT: Okay.

MR. LEE: For the record, we would move

at the close of the Plaintiffs' evidence for JMOL, and if I could articulate the grounds.

On infringement, we would move on the basis of Centocor has not performed the tests needed to prove competitive inhibition. The three tests that rely upon a comparison between Humira and cA2 are legally insufficient, particularly given the amendment to the file history that took that explicit comparison out and the testing of A2 that Humira was conducting.

As Your Honor knows, our contention is in the wrong direction, and for that reason, they have not satisfied the limitation of the claim.

I should say that even if Your Honor would find there would be enough to survive, from literal infringement purposes, there was no testimony under the Doctrine of Equivalents.

So at a minimum, equivalent infringement should go out, because no one offered any testimony on that ground, and that issue shouldn't go to the jury. On the issue of willful infringement, Your Honor, that is one where I think, given the burden of proof, which is clear and convincing on the part of Centocor, given the objectively reckless or objectively high standard that Seagate has given us all for whatever it is, we would suggest the following:

One, the fact that the '239 patent in its entirety and many of the claims of the '775 have gone out of the case as a result of Your Honor's ruling is a pretty good indication that we were not objectively reckless.

We'd also suggest the non-enablement, non-infringement, and anticipation argument, so I'm not going to reiterate them now, because they've been briefed to Your Honor, are sufficient under the Federal Circuit's post-Seagate law, that's not objectively reasonable.

And then, Your Honor, on the damages claim, we would move for JMOL only on the issue of lost profits in the event of an infringement. Centocor cannot claim lost profits on the sale for Humira for indications for Remicade for which it is not approved to treat. That is monotherapy. While there's some testimony about off-label use, that's not sufficient to satisfy the limitations.

And it cannot claim lost profits on licensed sales of Humira, or alternatively, sales that would have gone to Humira as a non-infringing substitute. So we would move on those grounds.

I would say candidly, Your Honor, knowing that I'm moving for the record, the two that I would

urge the Court to consider before the issues go to the jury in particular are the Doctrine of Equivalents to which there was no testimony, and, therefore, I don't think there should be any charge, and it can only be confusing, and the issue of willful infringement under Seagate.

THE COURT: Well, I'll take care of the Doctrine of Equivalents based on what I decide to charge the jury.

I'm interested, Ms. Elderkin, in what you've got to say about willful infringement, other than the fact -- you don't have to say it; I'll say it for you.

You know that the Federal Circuit may find that I was unreasonable in granting the motions for summary judgment, so they might say that those cases -- that should have been back in the case, and we'll all be back here again sometime.

But you don't need to say that; I will admit to that. They can make that ruling.

MS. ELDERKIN: We don't believe that -- we do believe we have made our proofs on willfulness for several reasons. We've proven that there is an objectively higher likelihood that Abbott infringes a valid patent.

First of all, our patent is presumed valid, and the fact that Centocor has stipulated to the invalidity of a number of the claims on the basis of Your Honor's summary judgment ruling has nothing to do with the four claims that remain.

Those four claims remain presumptively valid, and there's actually a case that's relevant on the point. It's the Eaton Corporation versus ZF Meritor, which is a 2008 U.S. District Lexis 26989 out of the Eastern District of Michigan. That is relevant on that point.

Dr. Adams presented testimony that Humira meets every element of Claims 2, 3, 14, and 15. No contrary evidence has been introduced.

In addition, we have proven that Abbott knew or should have known of the objectified -- objectively high risk that it would be infringing a valid patent.

Abbott was told about the allowed patent claims in December of 2005. It admits it was told about the allowed patent claims in December 2005.

Its 30(b)(6) witness, Ms. Lubbert, who was shown in video this morning, stated for the company that they knew about the issued patent shortly after it issued.

Mr. Scodari testified that his counterpart at Abbott, Mr. Dempsey, acknowledged in February 2006 that they could be challenged on infringement.

Its counsel, Mr. Conway, admitted that they knew that they could be sued.

There's evidence that he actually sought counsel from three different law firms after seeing the allowed patent claims.

There's evidence that he asked Abbott scientists, Zehra Kaymakcalan, for data, and that that was the same Remicade/Humira competition testing that our expert, Dr. Adams, relied upon and which shows infringement.

The jury can also infer from Mr. Conway, the in-house counsel's testimony, about the aggressive risk management strategy that Abbott engaged in with respect to Humira, that Abbott was aware of the objectively high likelihood that it infringed, and that it pursued its infringing activity nonetheless.

THE COURT: All right. The motion is denied.

Anything else?

MR. LEE: Your Honor, there's one legal issue on notice that I should have preserved, which is

the -- there's a question of whether notice of the allowed patent before issuance is sufficient. We've previously moved on the issue before, Your Honor. I would move again --

THE COURT: Okay.

MR. LEE: -- in order to preserve the issue.

THE COURT: It's denied.

Okay. Anything else that y'all need to talk to me about?

MR. SAYLES: Judge, do you think there's any chance we would argue this on Thursday?

THE COURT: Well, I don't know. Y'all tell me. If you're interested, you've used 7 hours and 12 minutes, and Defendants have used 4 hours and 15 minutes.

MR. SAYLES: I guess I will talk with them and see what they think.

THE COURT: I mean, I'm here, but the problem is I'm not going to be here nor are you, as I understand it, here Friday. And I know Mr. Beck is not going to be here, because we're all three going to be in the same place, is my understanding.

MR. SAYLES: Mr. Lee and Ms. Elderkin will be there as well as it turns out.

THE COURT: Oh, okay. Well, good.

MR. BECK: He can argue it there, Judge.

THE COURT: Off the record.

(Discussion off the record.)

THE COURT: How much time -- how many witnesses have you got? Getting back on the record.

MR. LEE: I think, Your Honor, we have -- we will call Dr. Mark -- we'll probably play about a half hour of video, a couple of witnesses.

We will have Dr. Marks, who probably will be on direct an hour and 45 minutes to two hours and then show about another half hour of video, and then we'll have -- our last live witness will be Mr. Slottje, who will be about an hour.

THE COURT: How much does that all total up?

MR. LEE: I think the honest answer is we have a good shot, depending on what they're going to do in rebuttal to getting most of it done tomorrow, but there's a chance it's going to go over into Thursday morning, I think.

THE COURT: Well, my thoughts would be that what we ought to do is get all the evidence in, get all the motions in, and get the charge finalized so that we roll out Monday morning.

That's when we do it, rather than -- you know, because we're not -- lead counsel doesn't want to be here during jury deliberations. I don't want to be here. We can have Judge Everingham preside Friday.

That's just not what we sort of worked out, unless y'all have got some reason that you want to break it up that way.

MR. SAYLES: I prefer to do it as you just suggested.

THE COURT: I think that will be better. You know, I was planning on finalizing that charge before I go to bed Thursday night.

So from what y'all are telling me, it sounds like maybe I can tell my wife I will be home for dinner on Thursday rather than being over here working on the charge that I seem to always be.

So that would be my thoughts is that we would get the charge finalized and take final objections to the charge on Thursday.

We'll try to get you a draft of the charge maybe by noon tomorrow.

MR. LEE: That's great.

THE COURT: So the way we'll do that is after you get that first draft, then we will probably meet late tomorrow afternoon and discuss with you at

this -- at this hour, after the jury goes home, what, as I describe it, in an informal charge conference in chambers what part of the charge is giving you the worst heartburn.

And whatever changes I'm going to make, I'll give you an idea what those will be. And then I will give you a final draft, and then we will let you make your formal objections to that before we leave here on Thursday.

And then that way, we can roll out of here -- roll out Monday morning with final arguments.

MR. LEE: Great.

THE COURT: Is that --

MR. LEE: That's great.

THE COURT: Ms. Elderkin?

MS. ELDERKIN: Nothing, Your Honor. Thank you.

THE COURT: Mr. Beck, do you have something?

MR. BECK: Just a question. Judge, I've forgotten. Do you charge the jury before argument or after?

THE COURT: After argument. You will have a complete copy of the charge. You can show them anything you want to that I've given you.

You can put any part of the charge on the screen and just tell them -- I mean, I've argued cases before where you couldn't do that, but you could say what you anticipate to the Court, but you can just tell them this is what -- you know, this is what the Court has told us he's going to tell you.

So that's the way I'll do it.

MR. BECK: Okay. Thank you.

THE COURT: So off -- could I see counsel up here just a moment?

The Court's in recess.

(Court adjourned.)

* * * * *

CERTIFICATION

I HEREBY CERTIFY that the foregoing is a true and correct transcript from the stenographic notes of the proceedings in the above-entitled matter to the best of my ability.

/s/_____ _____
SUSAN SIMMONS, CSR Date
Official Court Reporter
State of Texas No.: 267
Expiration Date: 12/31/10

/s/_____ _____
JUDITH WERLINGER, CSR Date
Deputy Official Court Reporter
State of Texas No.: 731
Expiration Date 12/31/10